

EPA REGISTRATION NUMBER 53053-23 – VOL. 1

PM-31



File in
Jacket

June 2, 2004

U.S. Environmental Protection Agency
OPP Document Processing
7504C, AD, Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

SUBJECT: BST Protectant RTU 50
EPA Registration No. 75497-4
Master Label - Final

Dear Sir/Madame:

Enclosed is the final Master Label for BST Protectant RTU 50 with the requested revisions/conditions per EPA OPP agency letter dated 5/19/04.

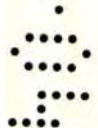
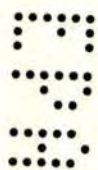
Please call me or Tim Moses at 770-650-6508 should you have any questions.

Sincerely,

Kimberly Casperson

Kimberly Casperson
General Manager

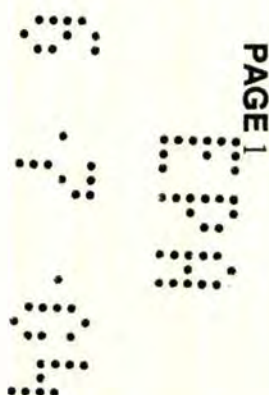
Nova BioGenetics Inc.
8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350 Ph: 770-650-6508 Fax: 770-650-0411





BST Protectant RTU 50

MICROBIOSTATIC AGENT*



Active Ingredient:	Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride.....	0.50%
Other Ingredients:	99.50%
TOTAL		
INGREDIENTS:	100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Lot No. _____

EPA Reg. No. 75497-4

EPA EST. XXXX-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, 32 or 36 fluid oz.; 0.5, 1, 5, 55, 150, 300, or 450 gal.

FIRST AID

Have the product container or label with you when calling the poison control center or a doctor, or going for treatment.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

* A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes and skin. Harmful if inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Commercial and industrial uses: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of BST Protectant RTU 50 can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BST Protectant RTU 50.

Residential use: This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of pesticide. Do not apply directly to water.

DIRECTIONS FOR USE

Approved commercial and industrial applications

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry.

BST Protectant RTU 50 can be applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques.

The substrate can be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.

BST Protectant RTU 50 when used as a concrete additive is added directly during concrete preparation. Use 60 fluid ounces per cubic feet of concrete. Addition of BST Protectant RTU 50 reduces deterioration of sewer pipes and manholes by inhibiting microbiologically induced corrosion.

Approved commercial and industrial applications

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent. BST Protectant RTU 50 can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) and algaestatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems
- Air filters/materials
- Aquarium filter material
- Bed sheets, blankets, and bedspreads
- Buffer pads (abrasive and polishing)
- Carpets and draperies
- Concrete additive for sewer pipes, manholes and concrete sewer structures; not to be used in treatment of storm drains
- Concrete additive for repair and renewal of sewer pipes and manholes and concrete sewer structures; not to be used in treatment of storm drains
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
- Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Men's underwear and outerwear
- Non-woven disposable diapers
- Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- Polyurethane and cellulose foam for household, industrial, and institutional sponges and mops
- Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
- Polyurethane foam used as a growth medium for non-food crops and plants
- Pre-moistened towlettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
- Sand bags, tents, tarpaulins, sails, and ropes
- Athletic and casual shoes
- Shoe insoles
- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
- Toilet tank and seat covers
- Umbrellas

- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, the wiping cloths do not impart pesticide properties
- Women's hosiery
- Women's intimate apparel

DIRECTIONS FOR USE

**Approved commercial applications in homes, offices, automobiles and institutions
e.g., schools, hospitals, daycare centers, churches, correctional facilities**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent. BST Protectant RTU 50 can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) and algaestatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems
- Air filters/materials
- Aquarium filter material
- Bed sheets, blankets, and bedspreads
- Buffer pads (abrasive and polishing)
- Carpets and draperies
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
- Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Men's underwear and outerwear
- Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- Polyurethane and cellulose foam for household, industrial, and institutional sponges and mops
- Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
- Polyurethane foam used as a growth medium for non-food crops and plants
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
- Sand bags, tents, tarpaulins, sails, and ropes
- Athletic and casual shoes
- Shoe insoles

- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
- Toilet tank and seat covers
- Umbrellas
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
- Women's hosiery
- Women's intimate apparel

For Pump Spray Application: Using pump sprayer, spray entire area 4" - 6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. One gallon of BST Protectant RTU 50 treats approximately 200 square feet. When treating coarser substrates, more BST Protectant RTU 50 may be required due to absorption. A fan may be used to assist in drying carpeting.

For Commercial Spray Application: For commercial application equipment (i.e., carpet/upholstery steamers, rotary jet extraction cleaners, pressure sprayers) apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. One gallon of BST Protectant RTU 50 treats approximately 200 square feet. When treating coarser substrates, more BST Protectant RTU 50 may be required due to absorption. Dry carpet areas and surfaces before re-entry and dry articles before use. A fan may be used to assist in drying carpeting.

For Dipping/Soaking Application: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Completely submerge item in solution for 3 minutes. Remove item and dry. Test for staining and color-fastness of fabrics by treating and drying a small, concealed area prior to application. Do not reuse solution after dipping/soaking.

The substrate can be dried at room temperatures or at temperatures to a maximum of 160° C (320° F), for example in a clothes dryer. Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.

DIRECTIONS FOR USE

For residential applications

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

Approved residential uses

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent.

	Pest controlled	Method of Application
<p>Bedsheets, blankets, bedspreads, curtains, draperies (washable only), underwear, socks, intimate apparel, hosiery, throw rugs, towelings, toilet tank covers, shower curtains, shoe insoles, outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos). BST Protectant RTU 50 can be applied to fabrics made of acetates, acrylics, cotton, fiberglass, linen, Lycra, nylon, orlon, polyester, polyethylene, polyolefins, polypropylene, rayon, silk, spandex, vinyl, and wool</p>	<p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for 3 minutes. Remove item and wring excess liquid. Drying may be attained by dripping dry or wringing excess liquid from treated item. For larger items (e.g., bedspreads, curtains, draperies), place in washing machine on spin cycle to aid in the removal of excess liquid. Test staining and color-fastness of fabric and carpets by treating and drying a small concealed area prior to application. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p> <p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p> <p>Method of Application</p>
<p>Air filters and air filter material for</p> <ul style="list-style-type: none"> • Furnaces, air conditioners • Air purification systems • Automobiles • Recirculating air handling systems • Vacuum cleaner filters • Aquariums 	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>SPRAY: When treating filters, remove filter from the unit. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Apply and then let stand until dry. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p> <p>Method of Application</p>
<p>Carpeting</p>	<p>Pest controlled</p> <p>odor causing</p>	<p>Method of Application</p> <p>SPRAY: Apply to clean carpet surface. Using a trigger pump sprayer or</p>

	bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. For rotary jet extraction cleaners and carpet steamers, add BST Protectant RTU 50 directly to the cleaning tank, then operate the equipment in accordance with manufacturer's instructions. Apply and then let stand until dry. Test staining and colorfastness of carpets by treating and drying a small concealed area prior to application. BST Protectant RTU 50 treats approximately 200 square feet per gallon (50 square feet per quart). When treating coarser substrates (e.g., wool carpeting), more BST Protectant RTU 50 may be required due to absorption. Dry carpet areas and surfaces before re-entry. A fan may be used to assist in drying carpeting. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.
	Pest controlled	Method of Application
Mattress pad and mattress ticking and upholstery composed of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool; fiberfill to be used in upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, rayon or wool	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	SPRAY: Clean surfaces prior to application. Using a trigger pump sprayer spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and colorfastness of fabric by treating and drying a small concealed area prior to application. When applying to mattress pads and ticking do not soak. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains and mildew stains return.
	Pest controlled	Method of Application
Tents, tarpaulins, sails, ropes	Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae	SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and colorfastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return. DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for three minutes. Remove item and wring excess liquid. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes

		dryer). Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
Roofing materials (such as shingles, roofing granules, wood shakes, felt, stone, synthetic overcoats)	Pest controlled Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae	Method of Application SPRAY: Make sure the roof is clean prior to application. Using a pressure sprayer, spray the entire surface area 6"-12" from the surface making sure the surface is completely covered. After applying BST Protectant RTU 50, let stand until dry. BST Protectant RTU 50 treats approximately 200 square feet of roofing per gallon (50 square feet per quart). If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
Buffer pads (polishing and abrasive), Polyurethane and cellulose foam for household sponges and mops, vacuum cleaner bags, umbrellas, casual shoes, athletic shoes	Pest controlled Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	Method of Application SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.
Tubs, glazed tiles, vanity tops, shower curtains, shower stalls (areas), sinks, washable walls, wall paper for non-food contact, floors, window sills, cabinets, garbage cans, appliances, refrigerators (exterior), fiberglass, formica, glazed tiles, glazed porcelain, synthetic marble, plastic, vinyl	Pest controlled Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	Method of Application SPRAY: Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.

Imparts microbiostatic properties.

Use on carpet and upholstery to inhibit odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew).
 Unscented.

Use on carpet and upholstery to inhibit the growth of odor causing bacteria.

Use on carpet and upholstery to inhibit the growth of bacteria which cause staining and discoloration.

Use on carpet and upholstery to inhibit the growth of fungi (mold and mildew).

Use on carpet and upholstery to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew).

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria.

Provides an invisible microbiostatic coating to inhibit the growth of bacteria which cause staining and discoloration.

Provides an invisible microbiostatic coating to inhibit the growth of fungi (mold and mildew).

Provides an invisible microbiostatic coating to inhibit the growth of algae.

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Prevents deterioration caused by bacteria and fungi (mold and mildew).
Inhibits deterioration caused by bacteria.

Resists development of microbial odors.

Resists development of stains and discoloration due to bacteria.

Resists development of stains due to fungi (mold and mildew).

Resists stains due to algae.

Resists development of microbial odors, stains and discoloration due to bacteria, fungi (mold and mildew), and algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria.

Provides/creates an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

Provides/creates an invisible barrier to inhibit the growth of fungi (mold and mildew).

Provides/creates an invisible barrier to inhibit the growth of algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Inhibits the growth of odor causing bacteria between cleanings.

Inhibits the growth of bacteria which cause staining and discoloration between cleanings.

Inhibits the growth of fungi (mold and mildew) between cleanings.

Inhibits the growth of algae between cleanings.

Inhibits the growth of odor causing bacteria which cause staining and discoloration, fungi (mold and mildew), and algae between cleanings.
Mold, mildew, odor protector and inhibitor.

BST Protectant RTU 50 is an antimicrobial agent effective against odor causing bacteria.

BST Protectant RTU 50 is an antimicrobial agent effective against bacteria which cause staining and discoloration.

BST Protectant RTU 50 is an antimicrobial agent effective against fungi (mold and mildew).

BST Protectant RTU 50 is an antimicrobial agent effective against algae.

BST Protectant RTU 50, an antimicrobial agent, controls the source of odors on surfaces in the home, in the bathroom, in the kitchen.

Bacteriostatic, fungistatic (mold and mildew), algaestatic.

BST Protectant RTU 50, an antimicrobial agent, inhibits smelly odors caused by mold and mildew that can grow even in the cleanest of homes.

BST Protectant RTU 50, an antimicrobial agent, inhibits the growth of odor causing bacteria.

Effective on hard non-porous washable bathroom and kitchen surfaces and fixtures around the home.

Effective on modern hard non-porous washable surfaces made of fiberglass, glazed porcelain, Formica®, stainless steel, synthetic marble.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site. [residential use]

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. [commercial/industrial use]

Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash. [residential use]

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities. [commercial/industrial use]

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING NOVA BIOGENETICS, INC. AT 8601 DUNWOODY PL., STE. 338, ATLANTA, GA 30350.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Nova BioGenetics, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use. NOVA BIOGENETICS SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch I

A	Completed by Product Manager						
PRODUCT REVIEWER: <u>Tracy Lantz</u>						RMB <u>1</u> TEAM <u>3</u>	
Description of Action: <u>Resubmission</u>						EPA File Symbol/Reg No.: <u>75497-4</u>	
Decision No. <u>342622</u>		Submission No. _____		Fee for Service Action Code: _____			
FQPA Action Code: <u>308</u>		Non-FQPA Action Code: <u>759265</u>		Fee for Service Fee: \$ _____			
	MONTH	DAY	YEAR				
APPLICATION DATE	04	01	2004				
EPA PIN DATE	04	20	2004				
VIEWER ASSIGNED DATE			2004				
DATE DUE TO PM			2004				
DATE DUE OUT OF AGENCY	7	19	2004				
Type of Data:	Product Chemistry <input type="checkbox"/>	Acute Toxicology <input type="checkbox"/>	Efficacy <input type="checkbox"/>	Environmental Fate <input type="checkbox"/>	Ecological Effects <input type="checkbox"/>	Chronic Toxicology <input type="checkbox"/>	Exposure <input type="checkbox"/>
<p>COMMENTS: <u>NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM.</u></p> <p><u>Resubmission - Give to Tracy</u></p>							
DP Barcode No(s): _____							
B	For Arctic Slope Contract Only						
Contractor: Arctic Slope			Contract No.: 0332		ARCTIC SLOPE/MANAGER		
Draft Task: Signature _____ (Est. hrs)			Final Task: Signature _____ (Total hrs)				
C	Reviewer's Comments:						
<p>Response Code: <u>17</u></p> <p>Response Date: <u>MAY 19 2004</u></p>							

Receipt for Section 3

S: 759265

Regulatory Type: Product Registration - Section 3 Resubmission: ☐ Yes ☒ No

Application Type: Amendment Fee For Service: ☐ Yes ☒ No



Company: 75497 NOVA BIOGENETICS, INC. V



Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #: 75497-4 Product Name: BST PROTECTANT RTU 50

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 01-Apr-2004  OPP Rec'd Date: 20-Apr-2004 

Front End Date: 23-Apr-2004  Risk Manager Send Date: 23-Apr-2004 

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

New Ingredient Request Date:
New Ingredient Received Date:
Signature Date:

Print Letter

Enter More Information

Receipt Content

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 19 2004

Mr. Timothy C. Moses
Senior VP
Nova BioGenetics, Inc.
8601 Dunwoody Pl., Suite 338
Atlanta, GA 30350

SUBJECT: BST Protectant RTU 50
EPA Registration Number: 75497-4
Application Dated: April 1, 2004
Receipt Date: April 20, 2004

Dear Mr. Timothy C. Moses:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below.

- Correct name of Active Ingredient as per Agency request

Conditions

In future submissions to the Agency, list all packaging sizes on the Application for Pesticide such that the application is in agreement with the label for this product.

Make the following revisions to the label:

1. As per PR Notice 2001-1 add the following statement to the First Aid section of the label: *"Have the product container or label with you when calling a poison control center or a doctor, or going for treatment."*
2. Correct the Directions for Use in Commercial and Industrial Applications by revising to agree with the last stamped label to read: *"Use 60 fluid ounces per cubic feet of concrete."*
3. Add the following clarification in each instance (3 times) that this language appears on your label: *"Polyurethane and cellulose foam for household, industrial and institution sponges and mops"* or simply *"and cellulose"* referring to the foam to be treated in the Approved Residential Use section.

CONCURRENCES

SYMBOL	7510C						
SURNAME	J. Lantz						
DATE	5/19/04						15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4. Delete the following surfaces from the Approved commercial applications in homes, offices, automobiles..." as they are not appropriate for these sites:

"Concrete additive for sewer pipes, manholes..."

"Concrete additive for repair and renewal of sewer pipes..."

"Non-woven disposable diapers"

"Pre-moistened towelettes and tissue wipes..."

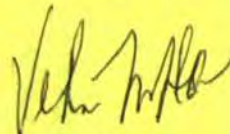
5. Revise the bullet on page 9 as follows: "Effective on modern hard non-porous washable surfaces *made of* fiberglass, glazed porcelain..."

6. Revise the Container Disposal statement to read exactly as follows such that the appropriate language is used for metal containers: "Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or *by other procedures approved by state and local authorities.*"

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
7510C:T.Lantz:5/17/04:75497-4a

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



BST Protectant RTU 50

MICROBIOSTATIC AGENT*

75497-4

Active Ingredient:	Octadecylaminodimethyltriethoxyethyl propyl ammonium chloride.....	0.50%
Other Ingredients:	99.50%
TOTAL	
INGREDIENTS:	100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

Lot No. _____ EPA Reg. No. 75497-4 EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, 32 or 36 fluid oz.; 0.5, 1, 5, 55, 150, 300, or 450 gal.

FIRST AID	
IF ON SKIN:	
• Take off contaminated clothing.	
• Rinse skin immediately with plenty of water for 15-20 minutes.	
• Call a poison control center or doctor for treatment advice.	
IF INHALED:	
• Move person to fresh air.	
• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.	
• Call a poison control center or doctor for further treatment advice.	
IF IN EYES:	
• Hold eye open and rinse slowly and gently with water for 15-20 minutes.	
• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.	
• Call poison control center or doctor for treatment advice.	
IF SWALLOWED:	
• Call a poison control center or doctor immediately for treatment advice.	
• Have person sip a glass of water if able to swallow.	
• Do not induce vomiting unless told to do so by a poison control center or doctor.	
• Do not give anything by mouth to an unconscious person.	

* A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes and skin. Harmful if inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Commercial and industrial uses: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of BST Protectant RTU 50 can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BST Protectant RTU 50.

Residential use: This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of pesticide. Do not apply directly to water.

DIRECTIONS FOR USE

Approved commercial and industrial applications

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry.

BST Protectant RTU 50 can be applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques.

The substrate can be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.

BST Protectant RTU 50 when used as a concrete additive is added directly during concrete preparation. Use 40 fluid ounces per cubic feet of concrete. Addition of BST Protectant RTU 50 reduces deterioration of sewer pipes and manholes by inhibiting microbiologically induced corrosion.

Approved commercial and industrial applications

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent. BST Protectant RTU 50 can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) and algaestatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems
- Air filters/materials
- Aquarium filter material
- Bed sheets, blankets, and bedspreads
- Buffer pads (abrasive and polishing)
- Carpets and draperies
- Concrete additive for sewer pipes, manholes and concrete sewer structures; not to be used in treatment of storm drains
- Concrete additive for repair and renewal of sewer pipes and manholes and concrete sewer structures; not to be used in treatment of storm drains
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
- Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Men's underwear and outerwear
- Non-woven disposable diapers
- Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- Polyurethane foam for household, industrial, and institutional sponges and mops
- Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
- Polyurethane foam used as a growth medium for non-food crops and plants
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
- Sand bags, tents, tarpaulins, sails, and ropes
- Athletic and casual shoes
- Shoe insoles
- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
- Toilet tank and seat covers
- Umbrellas

- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
- Women's hosiery
- Women's intimate apparel

DIRECTIONS FOR USE

**Approved commercial applications in homes, offices, automobiles and institutions
e.g., schools, hospitals, daycare centers, churches, correctional facilities**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent. BST Protectant RTU 50 can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) and algaestatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems
- Air filters/materials
- Aquarium filter material
- Bed sheets, blankets, and bedspreads
- Buffer pads (abrasive and polishing)
- Carpets and draperies
- Concrete additive for sewer pipes, manholes and concrete sewer structures; not to be used in treatment of storm drains
- Concrete additive for repair and renewal of sewer pipes and manholes and concrete sewer structures; not to be used in treatment of storm drains
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
- Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Men's underwear and outerwear
- Non-woven disposable diapers
- Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- Polyurethane foam for household, industrial, and institutional sponges and mops
- Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
- Polyurethane foam used as a growth medium for non-food crops and plants

- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
- Sand bags, tents, tarpaulins, sails, and ropes
- Athletic and casual shoes
- Shoe insoles
- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
- Toilet tank and seat covers
- Umbrellas
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
- Women's hosiery
- Women's intimate apparel

For Pump Spray Application: Using pump sprayer, spray entire area 4" - 6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. One gallon of BST Protectant RTU 50 treats approximately 200 square feet. When treating coarser substrates, more BST Protectant RTU 50 may be required due to absorption. A fan may be used to assist in drying carpeting.

For Commercial Spray Application: For commercial application equipment (i.e., carpet/upholstery steamers, rotary jet extraction cleaners, pressure sprayers) apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. One gallon of BST Protectant RTU 50 treats approximately 200 square feet. When treating coarser substrates, more BST Protectant RTU 50 may be required due to absorption. Dry carpet areas and surfaces before re-entry and dry articles before use. A fan may be used to assist in drying carpeting.

For Dipping/Soaking Application: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Completely submerge item in solution for 3 minutes. Remove item and dry. Test for staining and color-fastness of fabrics by treating and drying a small, concealed area prior to application. Do not reuse solution after dipping/soaking.

The substrate can be dried at room temperatures or at temperatures to a maximum of 160° C (320° F), for example in a clothes dryer. Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.

DIRECTIONS FOR USE

For residential applications

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

Approved residential uses

This active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent.

	Pest controlled	Method of Application
Bedsheets, blankets, bedspreads, curtains, draperies (washable only), underwear, socks, intimate apparel, hosiery, throw rugs, towelings, toilet tank covers, shower curtains, shoe insoles, outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos). BST Protectant RTU 50 can be applied to fabrics made of acetates, acrylics, cotton, fiberglass, linen, Lycra, nylon, orlon, polyester, polyethylene, polyolefins, polypropylene, rayon, silk, spandex, vinyl, and wool	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	<p>DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for 3 minutes. Remove item and wring excess liquid. Drying may be attained by dripping dry or wringing excess liquid from treated item. For larger items (e.g., bedspreads, curtains, draperies), place in washing machine on spin cycle to aid in the removal of excess liquid. Test staining and color-fastness of fabric and carpets by treating and drying a small concealed area prior to application. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p> <p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>
Air filters and air filter material for <ul style="list-style-type: none"> • Furnaces, air conditioners • Air purification systems • Automobiles • Recirculating air handling systems • Vacuum cleaner filters • Aquariums 	Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae	<p>Method of Application</p> <p>SPRAY: When treating filters, remove filter from the unit. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Apply and then let stand until dry. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>

	Pest controlled	Method of Application
Carpeting	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	SPRAY: Apply to clean carpet surface. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. For rotary jet extraction cleaners and carpet steamers, add BST Protectant RTU 50 directly to the cleaning tank, then operate the equipment in accordance with manufacturer's instructions. Apply and then let stand until dry. Test staining and colorfastness of carpets by treating and drying a small concealed area prior to application. BST Protectant RTU 50 treats approximately 200 square feet per gallon (50 square feet per quart). When treating coarser substrates (e.g., wool carpeting), more BST Protectant RTU 50 may be required due to absorption. Dry carpet areas and surfaces before re-entry. A fan may be used to assist in drying carpeting. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.
Mattress pad and mattress ticking and upholstery composed of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool; fiberfill to be used in upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, rayon or wool	Pest controlled Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	Method of Application SPRAY: Clean surfaces prior to application. Using a trigger pump sprayer spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and colorfastness of fabric by treating and drying a small concealed area prior to application. When applying to mattress pads and ticking do not soak. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains and mildew stains return.
Tents, tarpaulins, sails, ropes	Pest controlled Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae	Method of Application SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and colorfastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
		DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for three minutes. Remove item and

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site. **[residential use]**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **[commercial/industrial use]**

Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash. **[residential use]**

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. **[commercial/industrial use]**

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING NOVA BIOGENETICS, INC. AT 8601 DUNWOODY PL., STE. 338, ATLANTA, GA 30350.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

Nova BioGenetics, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use. NOVA BIOGENETICS SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

		<p>wring excess liquid. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p>
	Pest controlled	Method of Application
<p>Roofing materials (such as shingles, roofing granules, wood shakes, felt, stone, synthetic overcoats)</p>	<p>Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>SPRAY: Make sure the roof is clean prior to application. Using a pressure sprayer, spray the entire surface area 6"-12" from the surface making sure the surface is completely covered. After applying BST Protectant RTU 50, let stand until dry. BST Protectant RTU 50 treats approximately 200 square feet of roofing per gallon (50 square feet per quart). If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p>
	Pest controlled	Method of Application
<p>Buffer pads (polishing and abrasive), Polyurethane for household sponges and mops, vacuum cleaner bags, umbrellas, casual shoes, athletic shoes</p>	<p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>
	Pest controlled	Method of Application
<p>Tubs, glazed tiles, vanity tops, shower curtains, shower stalls (areas), sinks, washable walls, wall paper for non-food contact, floors, window sills, cabinets, garbage cans, appliances, refrigerators (exterior), fiberglass, formica, glazed tiles, glazed porcelain, synthetic marble, plastic, vinyl</p>	<p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>SPRAY: Using a trigger pump sprayer, spray the entire surface area 4" - 6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>

Imparts microbiostatic properties.

Use on carpet and upholstery to inhibit odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew). Unscented.

Use on carpet and upholstery to inhibit the growth of odor causing bacteria.

Use on carpet and upholstery to inhibit the growth of bacteria which cause staining and discoloration.

Use on carpet and upholstery to inhibit the growth of fungi (mold and mildew).

Use on carpet and upholstery to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew).

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria.

Provides an invisible microbistatic coating to inhibit the growth of bacteria which cause staining and discoloration.

Provides an invisible microbistatic coating to inhibit the growth of fungi (mold and mildew).

Provides an invisible microbistatic coating to inhibit the growth of algae.

Provides an invisible microbistatic coating to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Prevents deterioration caused by bacteria and fungi (mold and mildew).

Inhibits deterioration caused by bacteria.

Resists development of microbial odors.

Resists development of stains and discoloration due to bacteria.

Resists development of stains due to fungi (mold and mildew).

Resists stains due to algae.

Resists development of microbial odors, stains and discoloration due to bacteria, fungi (mold and mildew), and algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria.

Provides/creates an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

Provides/creates an invisible barrier to inhibit the growth of fungi (mold and mildew).

Provides/creates an invisible barrier to inhibit the growth of algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Inhibits the growth of odor causing bacteria between cleanings.

Inhibits the growth of bacteria which cause staining and discoloration between cleanings.

Inhibits the growth of fungi (mold and mildew) between cleanings.

Inhibits the growth of algae between cleanings.

Inhibits the growth of odor causing bacteria which cause staining and discoloration, fungi (mold and mildew), and algae between cleanings.

Mold, mildew, odor protector and inhibitor.

BST Protectant RTU 50 is an antimicrobial agent effective against odor causing bacteria.

BST Protectant RTU 50 is an antimicrobial agent effective against bacteria which cause staining and discoloration.

BST Protectant RTU 50 is an antimicrobial agent effective against fungi (mold and mildew).

BST Protectant RTU 50 is an antimicrobial agent effective against algae.

BST Protectant RTU 50, an antimicrobial agent, controls the source of odors on surfaces in the home, in the bathroom, in the kitchen.

Bacteriostatic, fungistatic (mold and mildew), algaestatic.

BST Protectant RTU 50, an antimicrobial agent, inhibits smelly odors caused by mold and mildew that can grow even in the cleanest of homes.

BST Protectant RTU 50, an antimicrobial agent, inhibits the growth of odor causing bacteria.

Effective on hard non-porous washable bathroom and kitchen surfaces and fixtures around the home.

Effective on modern hard non-porous washable surfaces like fiberglass, glazed porcelain, Formica®, stainless steel, synthetic marble.



April 1, 2004

U.S. Environmental Protection Agency
OPP Document Processing
7504C, AD, Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

SUBJECT: BST Protectant Concentrate C15
EPA Registration No. 75497-3
Master Label Amendment

Dear Sir/Madame:

Per a letter from your Antimicrobials Division (7510C - PM #31) dated September 3, 2003, we have changed the ingredient statement on the above referenced product from Otadecylaminodimethyltrimethoxysilyl to Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride as the active ingredient on our label. Per EPA letter dated 1/17/01, requested revisions/conditions in connection with registration under the FIFRA have been made. Three copies of the amended Master Label are enclosed.

Please call me or Tim Moses at 770-650-6508 should you have any questions.

Sincerely,

Kimberly Casperson
Kimberly Casperson
General Manager

...

...

Nova BioGenetics Inc.
8601 Dunwoody Place, Suite 338, Atlanta, Georgia 30350 Ph: 770-650-6508 Fax: 770-650-0411



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
75497

Application for Pesticide - Section I

1. Company/Product Number Nova BioGenetics Inc.	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BST Protectant Concentrate C15	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) 8601 Dunwoody Pl., Ste. 338 Atlanta, GA 30350 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>75497-3</u> Product Name <u>BST Protectant Concentrate C15</u>	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Per EPA letter dated 9/3/03, we have amended our ingredient statement to read octadecylaminodimethyltriethoxysilyl propyl ammonium chloride. Per EPA letter dated 1/17/01, we have made requested revisions/conditions in connection with registration under the FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container 2, 4, 8, 16, 20, 22,	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container N/A	5. Location of Label Directions <input type="checkbox"/> Labels on Container
--	------------------------------------	---

6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____
--	--------------------------------------

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Kimberly Casperson	Title General Manager	Telephone No. (Include Area Code) 770-650-6508
----------------------------	--------------------------	---

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Senior VP and COO
4. Typed Name Timothy C. Moses	5. Date

6. Date Application Received (Stamped)
--

HHN: Barbara Kurnell
(old No 70371)

Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved, GMS No. 2070-0044, Approval Expires 1-01-05

United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

32-25-1

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

75497-4

Distributor Company Number

11712

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

BST Protectant RTU 50

Distributor Product Name

Klean Shield

Name and Address of Distributor (Type; include ZIP code)

Kor-Chem, Inc.
P.O. Box 43163
5800 Bucknell Drive
Atlanta, GA 30336

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Sonya Zolbert, Chemist

Date

9/15/03

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

[Signature]

Date

10/24/03

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 3 - 2003

Ms. Jodi Martin
Nova Biogenetics, Inc.
8601 Dunwoody Place, Suite 338
Atlanta, GA 30350

SUBJECT: BioShield AM 500
EPA Registration No: 75497-1

BioShield AM 500 I
EPA Registration No: 75497-2

BST Protectant Concentrate C15
EPA Registration No: 75497-3

BST Protectant RTU 50
EPA Registration No: 75497-4

BST Protectant RTU 75
EPA Registration No: 75497-5

AM 3651PI
EPA Registration No: 75497-7

AM 3651P
EPA Registration No: 75497-8

Dear Ms. Martin:

It has come to our attention that the ingredients statement on the label of the above referenced products are incorrect. When Octadecylaminodimethyltrimethoxysilyl propyl ammonium chloride is added to water a reaction occurs resulting in Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride as the active ingredient.

Your last approved labels for each of these products identified the active ingredient in as 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

At your next label amendment, submit revised labeling to the Agency which indicates the correct active ingredient name for this product as Octadecylaminodimethyltrihydroxysilyl propyl ammonium chloride.

Should you have any questions concerning this letter and the labeling comments please contact Tracy Lantz at (703) 308-6415.

Sincerely,

A handwritten signature in dark ink, appearing to read "Velma Noble", written in a cursive style.

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

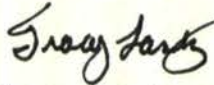
7510C:T.Lantz:8/26/03 correct name of AI 107401 products #3

NOTE TO THE JACKET

75497-1, -2, -3, -4, -5, -7, -8

8/26/03

Once the active ingredient name has been corrected for this product, the correct PC code must be assigned. This PC code should be in agreement with 48737-1.


Tracy Lantz
Team 31

BST Protectant RTU 50**MICROBIOSTATIC AGENT***

Active Ingredient:

3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride

0.5%

Other Ingredients:

99.5%

TOTAL

INGREDIENTS:

100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Lot No. _____

EPA Reg. No. 70871-4

EPA EST. xxxxx-GA-xx

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 17 2001

NET CONTENTS: 2, 4, 8, 16, 20, 22, 32 or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal

FIRST AIDUnder the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **70871-4****70871-4****IF ON SKIN:**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

* A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

May 7, 2003

Mr. Timothy C. Moses
President and CEO
Nova BioGenetics, Inc.
8383 Dunwoody Place, Bldg #3, Box 21
Atlanta, GA 30350

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Mr. Moses:

Subject: Transfer of Pesticide Registrations From
Company Number 70871 to Company Number 75497

Pursuant to your request in your letter and transfer agreement of January 31, 2003, we have approved the transfer of the following registrations from **BioShield Technologies, Inc.**, company number 70871, to **Nova BioGenetics, Inc.**, company number 75497.

The effective date of these changes is the date of this letter.

<u>Registered Products</u>	<u>Old EPA Reg. No.</u>	<u>New EPA Reg. No.</u>
BioShield AM 500	70871-1	75497-1
BioShield AM 500 I	70871-2	75497-2
BST Protectant Concentrate C15	70871-3	75497-3
BST Protectant RTU 50	70871-4	75497-4
BST Protectant RTU 75	70871-5	75497-5
BioShield BSTI 1860	70871-12	75497-6
AM 3651PI	70871-13	75497-7
AM 3651P	70871-15	75497-8

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer,

but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time

to submit, because they acquired the registration(s) after the 30 (2) (B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 30 (2) (B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,



Donna G. Parker
Information Management Specialist
Information Services Branch
Information Resources & Services Div. (7504C)

cc: Ms. Deirdre S. Baker, General Manager
BioShield Technologies, Inc.
4405 International Blvd., Suite B109
Norcross, GA 30093



Environmental Protection Agency

Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

970871-42

Distributor Company Number

5 65254

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

BST Protectant RTU 50

Distributor Product Name

Mold Guard

Name and Address of Distributor (Type; include ZIP code)

Emtech Laboratories, Inc.
580 Cemetery St.
Norcross, GA. 30071

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date

William L. Early President

12-9-02

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date

Deborah A. Bol Gm

12-11-02



United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

287750

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

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This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

70871-4 2

Distributor Company Number

57787 4

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

M500

Distributor Product Name

Great Lakes Mold & Mildew Inhibitor

Name and Address of Distributor (Type; include ZIP code)

Haviland Consumer Products, Inc.
421 Ann St.
Grand Rapids, MI 49504

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
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7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Michael J. Hannon, VICE PRESIDENT

Date

11/15/02

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Deborah L. Bol GM

Date

11/15/02

Please Read All Instructions Before Completing this Form (Form must be typed) Form Approved. OMB No. 2070-0044. Approval Expires 7-31-95



United States
Environmental Protection Agency
 Office of Pesticide Programs (7505C)
 Washington, DC 20480

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product 9 70871-4-11712	Distributor Company Number 11712 7
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Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA) BST Protectant RTU 50	Distributor Product Name Klean Shield
--	--

Name and Address of Distributor (Type; include ZIP code)

Kor-Chem, Inc.
 P.O. Box 43163 5800 Bucknell Drive
 Atlanta, GA 30336 Atlanta, GA 30336

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Smya Leckhart, Chemist

Date

8/28/02

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

[Signature]

Date

8/28/02



Environmental Protection Agency

Office of Pesticide Programs (7505C)
Washington, DC 20460

285315

7B2-21

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

9 70871-42

Distributor Company Number

1 4875

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

BST Protectant RTU 50

Distributor Product Name

INOCO RTU MicroStat .5%

Name and Address of Distributor (Type; include ZIP code)

INOCO Inc.
N. Railroad & Essex St.
P.O. Box 109
Gloucester City, NJ 08030

mg

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..." or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Judevick C. Britton

Date

3-5-02

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

[Signature]

Date

3-20-02

4-24-2002

284659 7B2-2



United States
Environmental Protection Agency
Office of Pesticide Programs (7505C)
Washington, DC 20460

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product 9 70871-4-1706	Distributor Company Number 1706
--	------------------------------------

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA) BST Protectant RTU 50	Distributor Product Name Biochek 505T
--	--

Name and Address of Distributor (Type; include ZIP code)

ONDEO Nalco Company
Ondeo Nalco Center
Naperville, IL 60563-1198

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor CLAUDE H. WOLF CORPORATE TOXICOLOGIST

Date
August 22, 2001

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant DR. MARCELO D. VILLANOZ Vice President

Date
8-30-01

3.15.2002



283678

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

9 70871-4 2

Distributor Company Number

4170 7

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

BST Protectant RTU 50

Distributor Product Name

Restrain Mold Inhibitor

Name and Address of Distributor (Type; include ZIP code)

Betco Corporation
1001 Brown Avenue
Toledo, Ohio 43607

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
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7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Carli R.

Date

11/24/01

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Angela B. Howell

Date

12/11/01

1:30.2002

FQPA

Reviewer ID

Tracy

Submission No.

S 587829

Data Package No.

FQPA

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 70871-4 PH 31

Action Code 302

10 Descriptor (Amend/Resubmissions only) _____

**Label
Amnd.**

5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No

15 Child-resistant Packaging

☐ (C) Certification

☐ (S) Service Person

20 Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

☐ (R) Non-residential Use Only

☐ (N) Not-Applicable

25 Proposed Classification: 30 Final Classification:

☐ (R) Restricted ☐ (R) Restricted

☐ (G) General ☐ (N) Not Classified

**Due Date
1/22/01**

35 Date on Application:

1 10 24 01
MO DAY YR

04 EPA Received Date:

1 10 24 01
MO DAY YR

40 Date Received by PM

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80 Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission

☐ (4) Not Applicable ☐ (7) Total Submission

☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

CH

EF

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DATE
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DATE
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RESPONSE
CODE

RESPONSE
DATE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BioShield Technologies, Inc.
4405 International Boulevard, Suite B-109
Norcross, GA 30093

JAN 17 2001

ATTENTION: Frederick T. Smith
Agent for BioShield

SUBJECT: BST Protectant RTU 50
EPA Registration Number: 70871-4
Your Amendment Dated: October 24, 2000
EPA Received Date: October 24, 2000

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. Revise the heading for the "Directions for Use" section on page two to read "Approved commercial and industrial applications".

B. Revise the heading for the "Directions for Use" section on page four to read "Approved commercial applications in homes, offices, automobiles and institutions e.g., schools, hospitals, daycare centers, churches, correctional facilities".

C. Your label must list the sites associated with the directions for use for "Approved commercial applications in homes, offices, automobiles and institutions e.g., schools, hospitals, daycare centers, churches, correctional facilities". Thus revise your label to include the following language:

"Approved commercial applications in homes, offices, automobiles and institutions e.g., schools, hospitals, daycare centers, churches, correctional facilities"

SYMBOL	7510C						
SURNAME	J. Landy						
DATE	1/17/01						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

The active ingredient in BST Protectant Concentrate C15 is effective against odor causing bacteria, bacteria which causes staining and discoloration, fungi (mold and mildew) and algae as a static agent.

BST Protectant Concentrate C15 can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic activity.

Air filters for furnaces, air conditioners, air purification devices, automobiles, recirculating air handling systems

Air filters/materials

Aquarium filter material

Bed sheets, blankets, and bedspreads

Buffer pads (abrasive and polishing)

Carpets and draperies

Fiberfill for upholstery, sleeping bags, apparel, where fiber is cotton, natural down, nylon, polyester, rayon or wool

Fiberglass ductboard

Fire hose fabric

Humidifier belts

Mattress pads and ticking

Men's underwear and outerwear

Non-woven polyester

Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)

Polyurethane foam for household, industrial, and institutional sponges and mops

Polyurethane and polyethylene foam when covered

Polyurethane foam for packaging and cushioning in non-food contact applications

Polyurethane foam used as a growth medium for non-food crops and plants

Roofing materials-defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats

Sand bags, tents, tarpaulins, sails, and ropes

Athletic and casual shoes

Shoe insoles

Shower curtains

Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra

Throw rugs

Toweling made of 100% cotton, 100% polyester, and blends of the two fibers

Toilet tank and seat covers

Umbrellas

Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool

Vacuum cleaner bags and filters

Vinyl paper-wallpaper for non-food contact surfaces

Disposable wiping clothes that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping clothes do not impart pesticide properties

REFERENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Women's hosiery

Women's intimate apparel

D. Add the following statement to page seven in the directions to treat tents, tarpaulins, sails, and ropes by the dip/soak method: *"Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application."*

E. Delete the final "Container Disposal" statement: "Securely wrap in original container in several layers of newspaper and discard in trash." as this language is a duplicate of previous language in this section.

2. Submit two (2) copies of your final printed labeling before you release the product for shipment.

A stamped copy of the labeling is enclosed for your records. Should you have any questions concerning this letter please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
7510C:T.Lantz:1/17/01:70871-4a

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

BST Protectant RTU 50

MICROBIOSTATIC AGENT*

Active Ingredient:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	0.5%
Other Ingredients:	99.5%
TOTAL		
INGREDIENTS:	100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 17 2001

EPA EST. xxxxx-GA-xx

EPA Reg. No. 70871-4

Lot No. _____

NET CONTENTS: 2, 4, 8, 16, 20, 32 or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 70871-4

FIRST AID

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

*A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

MASTER LABEL FOR BST PROTECTANT RTU 50

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with eyes and skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Commercial and industrial uses: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation may be required during clean up if a spill occurs. De-activation of BST Protectant RTU 50 can be achieved by the addition of anionic surfactant (such as soap, sulfonates, sulfates) in quantity equivalent to that of BST Protectant RTU 50.

Residential use: This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of pesticide. Do not apply directly to water.

DIRECTIONS FOR USE

For commercial and industrial applications

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry.

BST Protectant RTU 50 can be applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques.

The substrate can be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.

BST Protectant RTU 50 when used as a concrete additive is added directly during concrete preparation. Use 60 fluid ounces per cubic feet of concrete. Addition of BST Protectant RTU 50 reduces deterioration of sewer pipes and manholes by inhibiting microbiologically induced corrosion.

ACCEPTED
With COMMENTS
in EPA Letter Dated:
JAN 17 2001
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
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70871-4

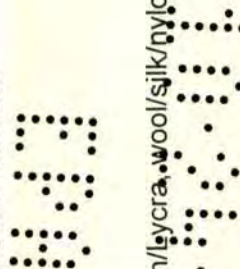
Approved commercial and industrial applications

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent. BST Protectant RTU 50 can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) and algaestatic activity.

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems
- Air filters/materials
- Aquarium filter material
- Bed sheets, blankets, and bedspreads
- Buffer pads (abrasive and polishing)
- Carpets and draperies
- Concrete additive for sewer pipes, manholes and concrete sewer structures; not to be used in treatment of storm drains
- Concrete additive for repair and renewal of sewer pipes and manholes and concrete sewer structures; not to be used in treatment of storm drains
- Fiberfill for upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, polyester, rayon, or wool
- Fiberglass ductboard
- Fire hose fabric
- Humidifier belts
- Mattress pads and ticking
- Men's underwear and outerwear
- Non-woven disposable diapers
- Non-woven polyester
- Outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos)
- Polyurethane foam for household, industrial, and institutional sponges and mops
- Polyurethane and polyethylene foam, when covered
- Polyurethane foam for packaging and cushioning in non-food contact applications
- Polyurethane foam used as a growth medium for non-food crops and plants
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties)
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats
- Sand bags, tents, tarpaulins, sails, and ropes
- Athletic and casual shoes
- Shoe insoles
- Shower curtains
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra
- Throw rugs
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers
- Toilet tank and seat covers
- Umbrellas

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in EPA Letter Dated:
JAN 17 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool
- Vacuum cleaner bags and filters
- Vinyl paper-wallpaper for non-food contact surfaces
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops; the wiping cloths do not impart pesticide properties
- Women's hosiery
- Women's intimate apparel

DIRECTIONS FOR USE

For commercial applications in homes, offices, automobiles and institutions e.g., schools, hospitals, daycare centers, churches, correctional facilities

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

For Pump Spray Application: Using pump sprayer, spray entire area 4"- 6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. One gallon of BST Protectant RTU 50 treats approximately 200 square feet. When treating coarser substrates, more BST Protectant RTU 50 may be required due to absorption. A fan may be used to assist in drying carpeting.

For Commercial Spray Application: For commercial application equipment (i.e. carpet/upholstery steamers, rotary jet extraction cleaners, pressure sprayers) apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. One gallon of BST Protectant RTU 50 treats approximately 200 square feet. When treating coarser substrates, more BST Protectant RTU 50 may be required due to absorption. Dry carpet areas and surfaces before re-entry and dry articles before use. A fan may be used to assist in drying carpeting.

For Dipping/Soaking Application: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Completely submerge item in solution for 3 minutes. Remove item and dry. Test for staining and color-fastness of fabrics by treating and drying a small, concealed area prior to application. Do not reuse solution after dipping/soaking.

The substrate can be dried at room temperatures or at temperatures to a maximum of 160° C (320° F), for example in a clothes dryer. Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacterial, mold, mildew, and algae stains return.

with COMMENTS
in EPA Letter Dated:

JAN 17 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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DIRECTIONS FOR USE
For residential applications

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application.

Approved residential uses

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae as a static agent.

	Pest controlled	Method of Application
<p>Bedsheets, blankets, bedspreads, curtains, draperies (washable only), underwear, socks, intimate apparel, hosiery, throw rugs, towelings, toilet tank covers, shower curtains, shoe insoles, outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos). BST Protectant RTU 50 can be applied to fabrics made of acetates, acrylics, cotton, fiberglass, linen, Lycra, nylon, orlon, polyester, polyethylene, polyolefins, polypropylene, rayon, silk, spandex, vinyl, and wool</p> <p style="text-align: right;"> ACCEPTED with COMMENTS in EPA Letter Dated: JAN 17 2001 <small>Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 70871-4</small> </p>	<p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for 3 minutes. Remove item and wring excess liquid. Drying may be attained by dripping dry or wringing excess liquid from treated item. For larger items (e.g., bedspreads, curtains, draperies), place in washing machine on spin cycle to aid in the removal of excess liquid. Test staining and color-fastness of fabric and carpets by treating and drying a small concealed area prior to application. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p> <p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry, or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply</p>

<p>Air filters and air filter material for</p> <ul style="list-style-type: none"> • Furnaces, air conditioners • Air purification systems • Automobiles • Recirculating air handling systems • Vacuum cleaner filters • Aquariums 	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p> <p>Method of Application</p> <p>SPRAY: When treating filters, remove filter from the unit. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"- 6" from the surface making sure the surface is completely covered. Apply and then let stand until dry. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p>
<p>Carpeting</p> <p>ACCEPTED with COMMENTS in EPA Letter Dated: JAN 17 2001</p> <p>Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 70871-4</p>	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>Method of Application</p> <p>SPRAY: Apply to clean carpet surface. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"- 6" from the surface making sure the surface is completely covered. For rotary jet extraction cleaners and carpet steamers, add BST Protectant RTU 50 directly to the cleaning tank, then operate the equipment in accordance with manufacturer's instructions. Apply and then let stand until dry. Test staining and color-fastness of carpets by treating and drying a small concealed area prior to application. BST Protectant RTU 50 treats approximately 200 square feet per gallon. When treating coarser substrates (e.g., wool carpeting), more BST Protectant RTU 50 may be required due to absorption. Dry carpet areas and surfaces before re-entry. A fan may be used to assist in drying carpeting. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>
<p>Mattress pad and mattress ticking and upholstery composed of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins.</p>	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause</p>	<p>Method of Application</p> <p>SPRAY: Clean surfaces prior to application. Using a trigger pump sprayer spray the entire surface area 4"- 6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and</p>

polypropylene, rayon, spandex, vinyl, wool; fiberfill to be used in upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, rayon or wool	staining and discoloration, and fungi (mold and mildew)	wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. When applying to mattress pads and ticking do not soak. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains and mildew stains return.
Tents, tarpaulins, sails, ropes	Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae	Method of Application SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
ACCEPTED with COMMENTS in EPA Letter Dated: JAN 17 2001 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 70871-4		DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for three minutes. Remove item and wring excess liquid. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
Roofing materials (such as shingles, roofing granules, wood shakes, felt, stone, synthetic overcoats)	Odor causing bacteria, bacteria which cause	Method of Application SPRAY: Make sure the roof is clean prior to application. Using a pressure sprayer, spray the entire surface area 6"-12" from the surface making sure the surface is completely covered. After applying BST Protectant RTU 50, let stand

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registered under EPA Reg. No. 70871-4

	staining and discoloration, fungi (mold and mildew), and algae	until dry. BST Protectant RTU 50 treats approximately 200 square feet of roofing per gallon. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
Pest controlled	Method of Application	
Buffer pads (polishing and abrasive), Polyurethane for household sponges and mops, vacuum cleaner bags, umbrellas, casual shoes, athletic shoes	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.
Pest controlled	Method of Application	
Tubs, glazed tiles, vanity tops, shower curtains, shower stalls (areas), sinks, washable walls, wall paper for non-food contact, floors, window sills, cabinets, garbage cans, appliances, refrigerators (exterior), fiberglass, formica, glazed tiles, glazed porcelain, synthetic marble, plastic, vinyl	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	SPRAY: Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.

Imparts microbiostatic properties.

Use on carpet and upholstery to inhibit odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew).

Unscented.

Use on carpet and upholstery to inhibit the growth of odor causing bacteria.

Use on carpet and upholstery to inhibit the growth of bacteria which cause staining and discoloration.

Use on carpet and upholstery to inhibit the growth of fungi (mold and mildew).

Use on carpet and upholstery to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria.

Provides an invisible microbiostatic coating to inhibit the growth of bacteria which cause staining and discoloration.

Provides an invisible microbiostatic coating to inhibit the growth of fungi (mold and mildew).

Provides an invisible microbiostatic coating to inhibit the growth of algae.

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Prevents deterioration caused by bacteria and fungi (mold and mildew).

Inhibits deterioration caused by bacteria.

Resists development of microbial odors.

Resists development of stains and discoloration due to bacteria.

Resists development of stains due to fungi (mold and mildew).

Resists stains due to algae.

Resists development of microbial odors, stains and discoloration due to bacteria, fungi (mold and mildew), and algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria.

Provides/creates an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

Provides/creates an invisible barrier to inhibit the growth of fungi (mold and mildew).

Provides/creates an invisible barrier to inhibit the growth of algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Mold, mildew, odor protector and inhibitor.

BST Protectant RTU 50 is an antimicrobial agent effective against odor causing bacteria.

BST Protectant RTU 50 is an antimicrobial agent effective against bacteria which cause staining and discoloration.

BST Protectant RTU 50 is an antimicrobial agent effective against fungi (mold and mildew).

BST Protectant RTU 50 is an antimicrobial agent effective against algae.

BST Protectant RTU 50, an antimicrobial agent, controls the source of odors on surfaces in the home, in the bathroom, in the kitchen.

Bacteriostatic, fungistatic (mold and mildew), algaestatic.

BST Protectant RTU 50, an antimicrobial agent, inhibits smelly odors caused by mold and mildew that can grow even in the cleanest of homes.

BST Protectant RTU 50, an antimicrobial agent, inhibits the growth of odor causing bacteria.

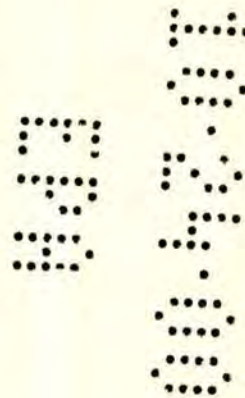
Effective on hard non-porous washable bathroom and kitchen surfaces and fixtures around the home.

Effective on modern hard non-porous washable surfaces like fiberglass, glazed porcelain, Formica®, stainless steel, synthetic marble.

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site. **[residential use]**
Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
[commercial/industrial use]

Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash. **[residential use]**
Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. **[commercial/industrial use]**

Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 17 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 70871-4

43

09.42.03

A

SciReg, Inc.
Science and Regulatory Consultants

B

October 24, 2000

Ms. Velma Noble
Document Processing Desk (AMEND)
Office of Pesticide Programs (7404C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

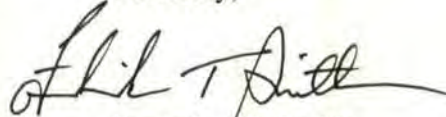
Re: BioShield Technologies, Inc.
- BST Protectant RTU 50 (Reg. No. 70871-4)
- Addition of Commercial/Industrial Uses

Dear Ms. Noble:

On behalf of BioShield Technologies, Inc., SciReg, Inc. is submitting an amendment and a revised label for the above-identified product to include commercial/industrial uses, in addition to the already approved residential uses. One copy of the approved master label, with deletions highlighted, and six copies of the revised label, of which one copy is also highlighted to identify the additions, are included herein.

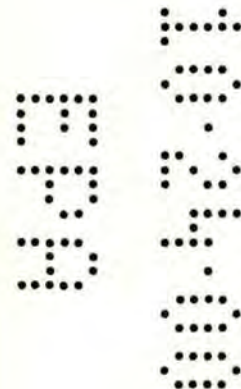
Should you have any questions, please call.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures





United States
Environmental Protection Agency
 Washington, DC 20460

☐ Registration
☒ **Amendment**
☐ Other

OPP Identifier Number

275258

Application for Pesticide - Section I

1. Company/Product Number 70871-4	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
3. Company/Product (Name) BST Protectant RTU 50	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)
 Addition of commercial/industrial uses.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Package wgt. No. Per Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
--	--	---	---

* **Certification must be submitted**

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2 - 36 oz.; 0.5, 1, 5, 55, 150, and 300 gal.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)		
Name Frederick T. Smith	Title Agent	Telephone No. (Include Area Code) (703) 494-6500
Certification I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Frederick T. Smith	5. Date 10/24/00	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

275258

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

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Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

275258
275258

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

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<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

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4. Typed Name		5. Date			

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3. **Proposed Classification** - Specify the proposed classification of this product.
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3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

FQPA

Reviewer ID

Tracy

Submission No.

5586331

Data Package No.

FQPA

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 70871-4 PH 31Action Code 302

Label

Review

|10| Descriptor (Amend/Resubmissions only)

|5| Intrastate Call-in ☐ (Y) Yes ☐ (N) No

|15| Child-resistant Packaging

☐ (C) Certification☐ (S) Service Person☐ (R) Non-residential Use Only☐ (N) Not-Applicable

|20| Registration Type:

☐ (1) Conditional☐ (2) Unconditional

|25| Proposed Classification: |30| Final Classification:

☐ (R) Restricted☐ (R) Restricted☐ (G) General☐ (N) Not Classified

Due Date:

12/28/00

90 days

|35| Date on Application:

01 9 219 010
MO DAY YR

|04| EPA Received Date:

01 9 219 010
MO DAY YR

|40| Date Received by PH

11 0 015 010
MO DAY YR

|80| Method of Support:

☐ (1) Cite-All☐ (6) Owner Submission☐ (4) Not Applicable☐ (7) Total Submission☐ (5) Not Submitted☐ (8) Selective Method

Reviewers Requested:

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

BST Protectant RTU 50

MICROBIOSTATIC AGENT*

Active Ingredient:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	0.5%
Other Ingredients:	99.5%
TOTAL		
INGREDIENTS:	100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Lot No. _____ EPA Reg. No. 70871-4 EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, 32 or 36 fluid oz.; 0.5, 1, or 5 gal.

FIRST AID	
IF ON SKIN:	
• Take off contaminated clothing.	
• Rinse skin immediately with plenty of water for 15-20 minutes.	
• Call a poison control center or doctor for treatment advice.	
IF INHALED:	
• Move person to fresh air.	
• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.	
• Call a poison control center or doctor for further treatment advice.	
IF IN EYES:	
• Hold eye open and rinse slowly and gently with water for 15-20 minutes.	
• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.	
• Call poison control center or doctor for treatment advice.	
IF SWALLOWED:	
• Call a poison control center or doctor immediately for treatment advice.	
• Have person sip a glass of water if able to swallow.	
• Do not induce vomiting unless told to do so by a poison control center or doctor.	
• Do not give anything by mouth to an unconscious person.	

* A microbistatc agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with eyes and skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of pesticide.

DIRECTIONS FOR USE

For Residential Use Only

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application. BST Protectant RTU 50 is ready to use; no dilution is required.

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent.

	Pest controlled	Method of Application
Bedsheets, blankets, bedspreads, curtains, draperies (washable only), underwear, socks, intimate apparel, hosiery, throw rugs, toweling, toilet tank covers, shower curtains, shoe insoles, outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos). • BST Protectant RTU 50 can be applied to fabrics made of acetates, acrylics, cotton, fiberglass, linen, Lycra, nylon, orlon, polyester, polyethylene, polyolefins, polypropylene, rayon, silk, spandex, vinyl, and wool	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for 3 minutes. Remove item and wring excess liquid. Drying may be attained by dripping dry or wringing excess liquid from treated item. For larger items (e.g., bedspreads, curtains, draperies), place in washing machine on spin cycle to aid in the removal of excess liquid. Test staining and color-fastness of fabric and carpets by treating and drying a small concealed area prior to application. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove excess

	<p>liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p> <p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>
<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>Method of Application</p> <p>SPRAY: When treating filters, remove filter from the unit. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Apply and then let stand until dry. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p>
<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>Method of Application</p> <p>SPRAY: Apply to clean carpet surface. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. For rotary jet extraction cleaners and carpet steamers, add BST Protectant RTU 50 directly to the cleaning tank, then operate the equipment in accordance with manufacturer's instructions. Apply and then let stand until dry. Test staining and color-fastness of carpets by treating and drying a small concealed area prior to application. BST Protectant RTU 50 treats approximately 200 square feet per gallon. When treating coarser substrates (e.g., wool carpeting), more BST Protectant RTU 50 may be</p>

		<p>required due to absorption. Dry carpet areas and surfaces before re-entry. A fan may be used to assist in drying carpeting. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>
	Pest controlled	Method of Application
<p>Mattress pad and mattress ticking and upholstery composed of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool; fiberfill to be used in upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, rayon or wool</p>	<p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>SPRAY: Clean surfaces prior to application. Using a trigger pump sprayer spray the entire surface area 4" - 6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. When applying to mattress pads and ticking do not soak. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains and mildew stains return.</p>
	Pest controlled	Method of Application
<p>Tents, tarpaulins, sails, ropes</p>	<p>Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p> <p>DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for three minutes. Remove item and wring excess liquid. Do not reuse solution after dipping/soaking. Dry</p>

		<p>treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p>
<p>Roofing materials (such as shingles, roofing granules, wood shakes, felt, stone, synthetic overcoats)</p>	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>Method of Application</p> <p>SPRAY: Make sure the roof is clean prior to application. Using a pressure sprayer, spray the entire surface area 6"-12" from the surface making sure the surface is completely covered. After applying BST Protectant RTU 50, let stand until dry. BST Protectant RTU 50 treats approximately 200 square feet of roofing per gallon. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p>
<p>Buffer pads (polishing and abrasive), Polyurethane for household sponges and mops, vacuum cleaner bags, umbrellas, casual shoes, athletic shoes</p>	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>Method of Application</p> <p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>
<p>Tubs, glazed tiles, vanity tops, shower curtains, shower stalls (areas), sinks, washable walls, wall paper for non-food contact, floors, window sills, cabinets, garbage cans, appliances, refrigerators (exterior), fiberglass, formica, glazed tiles, glazed porcelain, synthetic marble, plastic, vinyl</p>	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>Method of Application</p> <p>SPRAY: Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>

Imparts microbiostatic properties.

Use on carpet and upholstery to inhibit odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew).

Unscented.

Use on carpet and upholstery to inhibit the growth of odor causing bacteria.

Use on carpet and upholstery to inhibit the growth of bacteria which cause staining and discoloration.

Use on carpet and upholstery to inhibit the growth of fungi (mold and mildew).

Use on carpet and upholstery to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria.

Provides an invisible microbiostatic coating to inhibit the growth of bacteria which cause staining and discoloration.

Provides an invisible microbiostatic coating to inhibit the growth of fungi (mold and mildew).

Provides an invisible microbiostatic coating to inhibit the growth of algae.

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Prevents deterioration caused by bacteria and fungi (mold and mildew).

Inhibits deterioration caused by bacteria.

Resists development of microbial odors.

Resists development of stains and discoloration due to bacteria.

Resists development of stains due to fungi (mold and mildew).

Resists stains due to algae.

Resists development of microbial odors, stains and discoloration due to bacteria, fungi (mold and mildew), and algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria.

Provides/creates an invisible barrier to inhibit the growth of bacteria which cause staining and discoloration.

Provides/creates an invisible barrier to inhibit the growth of fungi (mold and mildew).

Provides/creates an invisible barrier to inhibit the growth of algae.

Provides/creates an invisible barrier to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Mold, mildew, odor protector and inhibitor.

BST Protectant RTU 50 is an antimicrobial agent effective against odor causing bacteria.

BST Protectant RTU 50 is an antimicrobial agent effective against bacteria which cause staining and discoloration.

BST Protectant RTU 50 is an antimicrobial agent effective against fungi (mold and mildew).

BST Protectant RTU 50 is an antimicrobial agent effective against algae.

BST Protectant RTU 50, an antimicrobial agent, controls the source of odors on surfaces in the home, in the bathroom, in the

Kitchen.

Bacteriostatic, fungistatic (mold and mildew), algaestatic.

BST Protectant RTU 50, an antimicrobial agent, inhibits smelly odors caused by mold and mildew that can grow even in the cleanest of homes.

BST Protectant RTU 50, an antimicrobial agent, inhibits the growth of odor causing bacteria.

Effective on hard non-porous washable bathroom and kitchen surfaces and fixtures around the home.

Effective on modern hard non-porous washable surfaces like fiberglass, glazed porcelain, Formica[®], stainless steel, synthetic marble.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site.

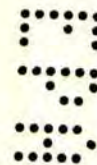
Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY



SciReg, Inc.
Science and Regulatory Consultants

September 29, 2000

Ms. Velma Noble
Product Manager 31
Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Re: BST Protectant RTU 50 (EPA Reg. No. 70871-4)

Dear Ms. Noble:

In accordance with the registration notice issued on September 27, 2000 for the above-identified product, enclosed please find one copy of the final master label. All changes requested in the registration notice have been incorporated. If you should have any questions regarding this submittal, please call.

Sincerely,



James S. Damico
President

Enclosures



Reviewer ID

Tracy

Submission No.

5587761

Data Package No.

FQPA

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 70871-4 PM 31

Action Code 332

Notification

10 Descriptor (Amend/Resubmissions only)

5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No

15 Child-resistant Packaging

☐ (C) Certification

☐ (S) Service Person

☐ (R) Non-residential Use Only

☐ (N) Not-Applicable

30 days

20 Registration Type:

☐ (1) Conditional

☐ (2) Unconditional

25 Proposed Classification: 30 Final Classification:

☐ (R) Restricted

☐ (R) Restricted

☐ (G) General

☐ (N) Not Classified

Due Date:

11/26/00

35 Date on Application:

11 MO 02 DAY 15 YR

04 EPA Received Date:

11 MO 02 DAY 17 YR

40 Date Received by PM

11 MO 01 DAY 06 YR

80 Method of Support:

☐ (1) Cite-All

☐ (6) Owner Submission

☐ (4) Not Applicable

☐ (7) Total Submission

☐ (5) Not Submitted

☐ (8) Selective Method

Reviewers Requested:

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

DATE SENT

DUE DATE

DATE RETURNED

RESPONSE CODE

RESPONSE DATE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 16 2000

BioShield Technologies, Inc.
4405 International Boulevard, Suite B-109
Norcross, GA 30093

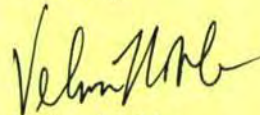
ATTENTION: Donna M. Ross

SUBJECT: BST Protectant 50
EPA Registration Number: 70871-4
Your Notification Dated: October 25, 2000
EPA Received Date: October 27, 2000

This is to acknowledge receipt of your notification as per PR Notice 98-10 to add the alternate brand name "DuraLast Protectant." This application is acceptable and the notification will be made part of the record for this file.

Should you have any questions concerning this letter please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

7510C: T. Lantz: 11/15/00: 70871-4a		CONCURRENCES					
SYMBOL	7510C						
SURNAME	T. Lantz						
DATE	11/15/00						



October 25, 2000

Ms. Velma Nobel (PM 31)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504-C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Via Federal Express Delivery

**Re: Notification of Alternate Brand Name
BST Protectant RTU 50 (EPA Registration No. 70871-4)**

Dear Ms. Noble:

BioShield Technologies, Inc. is submitting this notification for an Alternate Brand Name for our **BST Protectant RTU 50 (EPA Registration No. 70871-4)**.

The alternate brand name is :

- DuraLast Protectant

Also enclosed with this letter is an application for registration (EPA form 8570-1) as required per PR notice 98-10. If you have any questions, please contact me at (770)-246-2506.

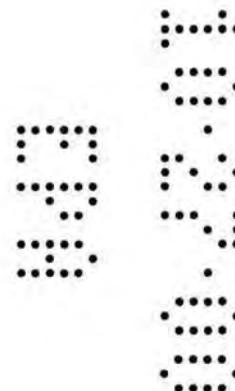
Sincerely,

A handwritten signature in black ink, appearing to read "Donna M. Ross".

Donna M. Ross
Director, Regulatory Affairs
BioShield Technologies, Inc.

Enclosure

Cc: BST RTU 50Files





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70871-4	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BST Protectant RTU 50	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) BioShield Technologies, Inc. 4405 International Blvd. Suite B-109 Norcross, GA 30093 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Notification of Alternate Brand Name per PR Notice 98-10." *This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2oz - 5gal		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name DONNA M. ROSS		Title DIRECTOR, REGULATORY AFFAIRS	
		Telephone No. (Include Area Code) (770) 246-2506	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title DIRECTOR, REGULATORY AFFAIRS	
4. Typed Name DONNA M. ROSS		5. Date 10-25-00	
6. Date Application Received (Stamped)			

NOTE TO THE JACKET

70871-3, -4, -5

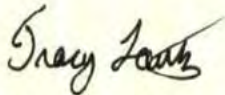
9/26/00

Prior to releasing the registration notices for these products I had a phone conversation with James Damico regarding two CSF issues. In the future I asked that the source of the water be identified as [REDACTED] or [REDACTED] not [REDACTED] and that the certified limits regardless of whether nominal concentrations were appropriate, always be based on the certified limits table.

The registrant will likely have concerns regarding the following comment in the registration notice: On page six delete the series of statements which begin "Molecularly bonds to...". These statements are unacceptable because they imply that a true chemical bond occurs between the substrate (fabric, carpet, upholstery or other surface) and your product.

Neither Nancy Whyte or Najm Shamim were in agreement with these statements from a chemistry standpoint. I will suggest to the registrant if we are contacted regarding this comment that acceptable wording would be as follows:

"This product forms linkages to fabrics..."



Tracy Lantz
Team 31

FQPA

Reviewer ID

Submission No.

Data Package No.

Tracy
5563728

FQPA

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 70871-4 PM 31 Action Code 187

|10| Descriptor (Amend/Resubmissions only) _____

|5| Intrastate Call-in ☐ (Y) Yes ☐ (N) No |15| Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person

|20| Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable

|25| Proposed Classification: ☐ (R) Restricted ☐ (G) General |30| Final Classification: ☐ (R) Restricted ☐ (N) Not Classified

Due Date:
10/18/00

|35| Date on Application: 016 210 010 |04| EPA Received Date: 016 210 00 |40| Date Received by PM: 016 217 010
MO DAY YR MO DAY YR MO DAY YR

|80| Method of Support: ☐ (1) Cite-All ☐ (6) Owner Submission ☐ (4) Not Applicable ☐ (7) Total Submission ☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

DATE
SENT

DUE
DATE

DATE
RETURNED

RESPONSE
CODE

RESPONSE
DATE

|115| FINAL Response ACTION Code 18

|120| Response

SEP 27, 2000

MO DAY YR

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg.
Number:
70871-4

Date of Issuance:
SEP 27 2000

NOTICE OF PESTICIDE:
 x Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:
CONDITIONAL

Name of Pesticide Product:
BST Protectant RTU 50

Name and Address of Registrant (include ZIP Code):

BioShield Technologies, Inc.
4405 International Boulevard, Suite B 109
Norcross, GA 30093

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Add the phrase EPA Registration Number "EPA Reg. No. 70871-4".

Signature of Approving Official:

Velma Noble

Velma Noble
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Date:

SEP 27 2000

EPA Form 8570-6

CONCURRENCES

SYMBOL	<i>9/26/00</i>						
SURNAME	<i>9/26/00</i>						
DATE	<i>7510C</i>						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL **78** LE COPY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

page 2
EPA Reg. No. 70871-4

3. This product has been registered as a microbiostatic agent for materials preservation only; neither this product, nor articles treated with this product, may state or imply any public health claims.

4. Articles or substances treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) only if the intended use for incorporating this material into the treated article or substance is for protection of the article or substance itself.

The following comments apply to the master label.

1. On page one, increase the font size of the asterisk (*) after "Microbiostatic Agent" and before "A microbiostatic agent is an agent that inhibits..."

2. On page two, include the phrase "For Residential Use Only."

3. On page three in the section describing the use of this product on carpeting, revise the statement to read "Test staining and color-fastness of carpets by treating and drying a small concealed area prior to application." deleting the phrase "fabric and".

4. On page six delete the series of statements which begin "Molecularly bonds to...". These statements are unacceptable because they imply that a true chemical bond occurs between the substrate (fabric, carpet, upholstery or other surface) and your product.

5. On pages six and seven revise the statements which begin "Provides/creates an invisible barrier against the..." to read "Provides/creates an invisible barrier to inhibit the..." deleting the word "against" which implies heightened efficacy for this microbiostatic compound.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

page 3
EPA Reg. No. 70871-4

A stamped copy of the master label is enclosed for your records. Submit one (1) copy of the final printed label prior to the release of the product for shipment.

If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

A handwritten signature in cursive script, reading "Velma Noble".

Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure: Stamped Label
7510C:T.Lantz:9/22/00:70871-4

BST Protectant RTU 50

MICROBIOSTATIC AGENT*

Active Ingredient:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	0.5%
Other Ingredients:	99.5%
TOTAL		
INGREDIENTS:	100.0%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 27 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 70871-4

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Lot No. _____ EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, 32 or 36 fluid oz.; 0.5, 1, or 5 gal.

FIRST AID	
IF ON SKIN:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

*A microbiostatic agent is an agent that inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. This product does not protect users or others against food-borne or disease-causing bacteria.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with eyes and skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of pesticide.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Wear protective eyewear (goggles or face shield) and gloves when using this product. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry. Clean surfaces prior to application. BST Protectant RTU 50 is ready to use; no dilution is required.

The active ingredient in BST Protectant RTU 50 is effective against odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew) and algae as a static agent.

	Pest controlled	Method of Application
Bedsheets, blankets, bedspreads, curtains, draperies (washable only), underwear, socks, intimate apparel, hosiery, throw rugs, toweling, toilet tank covers, shower curtains, shoe insoles, outerwear apparel (jackets, sweaters, sweatshirts, coats, raincoats, overcoats, jerseys, ponchos). BST Protectant RTU 50 can be applied to fabrics made of acetates, acrylics, cotton, fiberglass, linen, Lycra, nylon, orlon, polyester, polyethylene, polyolefins, polypropylene, rayon, silk, spandex, vinyl, and wool	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for 3 minutes. Remove item and wring excess liquid. Drying may be attained by dripping dry or wringing excess liquid from treated item. For larger items (e.g., bedspreads, curtains, draperies), place in washing machine on spin cycle to aid in the removal of excess liquid. Test staining and color-fastness of fabric and carpets by treating and drying a small concealed area prior to application. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer) Remove excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 27 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
Amended, for the pesticide,

registered under EPA Reg. No.

70871-4

		<p>bacteria, mold stains, and mildew stains return.</p> <p>SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p>
<p>Air filters and air filter material for</p> <ul style="list-style-type: none"> • Furnaces, air conditioners • Air purification systems • Automobiles • Recirculating air handling systems • Vacuum cleaner filters • Aquariums 	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>Method of Application</p> <p>SPRAY: When treating filters, remove filter from the unit. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Apply and then let stand until dry. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p>
<p>Carpeting</p>	<p>Pest controlled</p> <p>Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>Method of Application</p> <p>SPRAY: Apply to clean carpet surface. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. For rotary jet extraction cleaners and carpet steamers, add BST Protectant RTU 50 directly to the cleaning tank, then operate the equipment in accordance with manufacturer's instructions. Apply and then let stand until dry. Test staining and color-fastness of fabric and carpets by treating and drying a small concealed area prior to application. BST Protectant RTU 50 treats approximately 200 square feet per gallon. When treating coarser substrates (e.g., wool carpeting), more BST Protectant RTU 50 may be required due to absorption. Dry carpet areas and surfaces before re-entry. A fan may be used to assist in drying carpeting. Remove children and pets from treated area until</p>

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 27 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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70871-4

<p>Mattress pad and mattress ticking and upholstery composed of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, wool; fiberfill to be used in upholstery, sleeping bags, apparel, where the fiber is cotton, natural down, nylon, rayon or wool</p>	<p>Pest controlled Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)</p>	<p>completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.</p> <p>Method of Application SPRAY: Clean surfaces prior to application. Using a trigger pump sprayer spray the entire surface area 4" - 6" from the surface making sure the surface is completely covered. Apply and then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. When applying to mattress pads and ticking do not soak. Remove children and pets from treated area until completely dried. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains and mildew stains return.</p>
<p>Tents, tarpaulins, sails, ropes</p>	<p>Pest controlled Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae</p>	<p>Method of Application SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test staining and color-fastness of fabric by treating and drying a small concealed area prior to application. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.</p> <p>DIP/SOAK: Use appropriate sized wash basin or tub for dipping/soaking the item you are treating. Use enough BST Protectant RTU 50 to completely submerge item. Keep item in solution for three minutes. Remove item and wring excess liquid. Do not reuse solution after dipping/soaking. Dry treated articles before use. Substrates can be hang-dried at room temperature or at temperatures to a maximum of 160 °C (320 °F); (for example in a clothes dryer). Remove</p>

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 27 1977

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

70871-4

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 27 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

70871-4

		excess liquid before attempting to dry in a clothes dryer. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
	Pest controlled	Method of Application
Roofing materials (such as shingles, roofing granules, wood shakes, felt, stone, synthetic overcoats)	Odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae	SPRAY: Make sure the roof is clean prior to application. Using a pressure sprayer, spray the entire surface area 6-12" from the surface making sure the surface is completely covered. After applying BST Protectant RTU 50, let stand until dry. BST Protectant RTU 50 treats approximately 200 square feet of roofing per gallon. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, mildew stains, and algae stains return.
	Pest controlled	Method of Application
Buffer pads (polishing and abrasive), Polyurethane for household sponges and mops, vacuum cleaner bags, umbrellas, casual shoes, athletic shoes	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	SPRAY: Clean surface prior to application. Using a trigger pump sprayer or pressure sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.
	Pest controlled	Method of Application
Tubs, glazed tiles, vanity tops, shower curtains, shower stalls (areas), sinks, washable walls, wall paper for non-food contact, floors, window sills, cabinets, garbage cans, appliances, refrigerators (exterior), fiberglass, formica, glazed tiles, glazed porcelain, synthetic marble, plastic, vinyl	Odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew)	SPRAY: Using a trigger pump sprayer, spray the entire surface area 4"-6" from the surface making sure the surface is completely covered. Let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. If necessary, reapply BST Protectant RTU 50 every three months or when odor, staining and discoloration due to bacteria, mold stains, and mildew stains return.

Imparts microbiostatic properties.

Use on carpet and upholstery to inhibit odor causing bacteria, bacteria which cause staining and discoloration, and fungi (mold and mildew).

[REDACTED]

Use on carpet and upholstery to inhibit the growth of bacteria which cause staining and discoloration.

Use on carpet and upholstery to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Provides an invisible microbiostatic coating to inhibit the growth of bacteria which cause staining and discoloration.

Provides an invisible microbiostatic coating to inhibit the growth of algae.

Provides an invisible microbiostatic coating to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Inhibits deterioration caused by bacteria.

Resists development of stains and discoloration due to bacteria.

Resists stains due to algae.

Provides/creates an invisible barrier against the growth of odor causing bacteria.

Provides/creates an invisible barrier against the growth of fungi (mold and mildew).

Provides/creates an invisible barrier against the growth of algae.

SEP 27 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

70871-4

Provides/creates an invisible barrier against the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae.

Mold, mildew, odor protector and inhibitor.

BST Protectant RTU 50 is an antimicrobial agent effective against odor causing bacteria.

BST Protectant RTU 50 is an antimicrobial agent effective against bacteria which cause staining and discoloration.

BST Protectant RTU 50 is an antimicrobial agent effective against fungi (mold and mildew).

BST Protectant RTU 50 is an antimicrobial agent effective against algae.

BST Protectant RTU 50, an antimicrobial agent, controls the source of odors on surfaces in the home, in the bathroom, in the kitchen.

Bacteriostatic, fungistatic (mold and mildew), algaestatic.

BST Protectant RTU 50, an antimicrobial agent, inhibits smelly odors caused by mold and mildew that can grow even in the cleanest of homes.

BST Protectant RTU 50, an antimicrobial agent, inhibits the growth of odor causing bacteria.

Effective on hard non-porous washable bathroom and kitchen surfaces and fixtures around the home.

Effective on modern hard non-porous washable surfaces like fiberglass, glazed porcelain, Formica®, stainless steel, synthetic marble.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site.

Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

ACCEPTED
with COMMENTS
in a secure area inaccessible to children

SEP 27 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY

SciReg, Inc.

Science and Regulatory Consultants

August 28, 2000

Ms. Velma Noble
Product Manager 31
Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

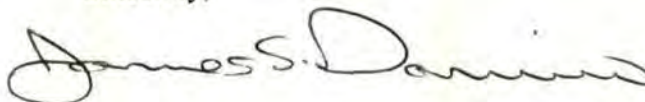
Re: BST Protectant RTU 50 (EPA File Symbol No. 70871-U)

Dear Ms. Noble:

Per my telephone conversation with Ms. Tracy Lantz this morning, enclosed please find two copies of the revised Confidential Statement of Formula for the above-identified product. Changes were made to explicitly identify the nominal concentration and upper/lower certified limits for the active ingredient. Additionally, a typographical error in the CAS number for the active ingredient was corrected.

If you should have any questions regarding this submittal, please call.

Sincerely,



James S. Damico
President

Enclosures

SciReg, Inc.

Science and Regulatory Consultants

August 10, 2000

Ms. Velma Noble
Document Processing Desk
Office of Pesticide Programs (7404C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Re: BioShield Technologies, Inc.
- BST Protectant RTU 50 (File Symbol 70871-U)
- Revised label

Dear Ms. Noble:

Attached please find five copies of the draft label for BST Protectant RTU 50, revised in accordance with the Agency's July 13, 2000 label comments for AM 500 (Reg. No. 70871-1) and for consistency with the AM 500 homeowner uses. The submitted labels supersede those submitted to the Agency on June 20, 2000.

Should you have any questions, please call.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

401 M Street, S.W.

Washington, D.C. 20460

DATA MATRIX

Date	Applicant's/Registrant's Name & Address	EPA Reg No. / File Symbol	Page		
6/20/00	BioShield Technologies, Inc. 4405 International Blvd., Suite B109 Norcross, GA 30093	Product BST Protectant RTU 50	1 of 2		
Ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550 (158.155)	Prod. identity/composition	44376201 ✕	BioShield	OWN	
830.1600 (158.160)	Desc. of beginning materials	"	"	"	
830.1620 (158.162)	Manufacturing process	"	"	"	
830.1670 (158.167)	Desc. of form. of impurities	"	"	"	
830.1750 (158.175)	Certified limits	44376202 ✕	"	"	
830.1800 (158.180)	Enforcement analytical method	"	"	"	
830.6302 (63-2)	Color	44376203 ✕	"	"	
830.6303 (63-3)	Physical state	"	"	"	
830.6304 (63-4)	Odor	"	"	"	
830.7000 (63-12)	pH	"	"	"	
830.7100 (63-18)	Viscosity	"	"	"	
830.7300 (63-7)	Density/bulk den./rel. den.	"	"	"	
870.1100 (81-1)	Acute oral toxicity	40385201 ✕	Dow Corning	PAY	
870.1200 (81-2)	Acute dermal toxicity	" ✕	"	"	
870.1300 (81-3)	Acute inhalation toxicity	41157803 ✕	"	"	
870.2400 (81-4)	Primary eye irritation	44789801 ✕	BioShield	OWN	
870.2500 (81-5)	Primary dermal irritation	40385201 ✕	Dow Corning	PAY	
870.2600 (81-6)	Dermal sensitization	42197401 ✕	"	"	

Signature _____

Signature _____

Name and Title	James S. Damico, President, SciReg, Inc. (Agent)
----------------	--

Date _____

Date 6/20/00

Washington, D.C. 20460

DATA MATRIX

[illegible]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

 401 M Street, S.W.
 WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant/Registrant's Name, Address, and Telephone Number BioShield Technologies, Norcross, GA 770-925-3432	EPA Registration Number/File Symbol 70871-U
Active ingredient(s) and/or representative test compound(s) 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride	Date 6/20/00
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Antimicrobial	Product Name BST Protectant RTU 50

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements.

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is used in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and use.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (f) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Donna M. Ross</i>	Date 6/20/00	Typed or Printed Name and Title Donna M. Ross Mgr. Microb./Reg. Affairs
-----------------------------------	------------------------	---

TRANSMITTAL DOCUMENT

Submitter

BioShield Technologies, Inc.
4405 International Blvd., Suite B109
Norcross, GA 30093

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

* SciReg, Inc. is the authorized agent for BioShield Technologies, Inc.

Regulatory action in support of which this package is submitted

BST Protectant RTU 50 (EPA File Symbol No. 70871-U): response to EPA letter dated
July 15, 1999

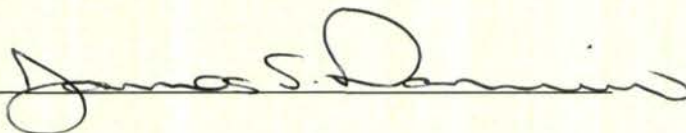
Transmittal Date

June 20, 2000

Contents

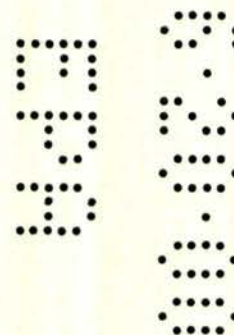
Vol. 1 Administrative Materials

Company Official: James S. Damico



Company Name: SciReg, Inc.

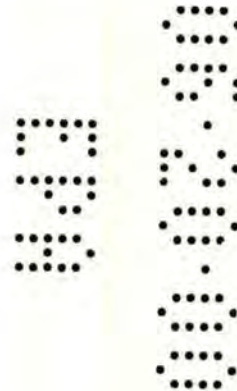
Company Contact: James S. Damico (703) 494-6500



SciReg, Inc.
Science and Regulatory Consultants

June 20, 2000

Ms. Velma Noble
Product Manager 31
Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501



Re: BST Protectant RTU 50 (EPA File Symbol No. 70871-U)

Dear Ms. Noble:

On behalf of BioShield Technologies, Inc., SciReg, Inc. is submitting this letter, and associated documents, in response to your July 15, 1999 letter (Noble to Damico). As we have previously discussed, because BST Protectant RTU 50 is intended for homeowner use, BioShield elected to postpone a response to your letter until 1) the Agency agreed that homeowner use of the active ingredient in the product is acceptable, and 2) EPA and BioShield had significantly agreed upon the homeowner use directions for AM 500 (EPA Reg. No. 70871-1) [BST Protectant RTU 50 is a water dilution of AM 500 I (EPA Reg. No. 70871-2) which is identical to AM 500].

Since the above two conditions appear to be satisfied, enclosed please find:

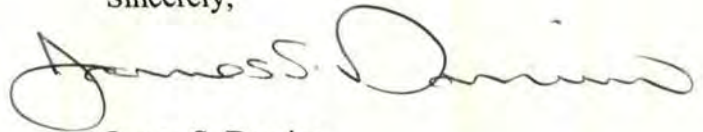
1. Revised Confidential Statement of Formula,
2. Certification with Respect to Citation of Data form, and associated data matrix,
3. Five copies of the revised label; the directions for use are based on the amended AM 500 label (submitted to EPA on May 25, 2000). All other changes requested in your July 15 letter have been made, with the following exceptions:
 - Under "Hazards to Humans and Domestic Animals," the statement, "Avoid contact with eyes, skin, or clothing," has been changed to "Avoid contact with eyes and skin" for consistency with the AM 500 label, and because the product is intended to treat clothing.
 - The "First Aid" statements are not the same as those identified in your letter. Instead first aid statements consistent with the recently-issued PR Notice 2000-3 are included.
 - The word, "protectant," remains in the product name. Products treated with BST Protectant RTU 50 will fall under the definition of "treated articles" and the word

Damico to Noble
June 20, 2000
p. 2

"protect" is a key component of the definition of treated articles (see 40 CFR, Part 152.25; "An article...treated with, or containing, a pesticide to *protect* the treated article..." [emphasis added]). Further, in accordance with PR Notice 2000-1, we have added language to the label that explicitly and clearly indicates the product "does not protect the user or others against food-borne or disease-causing bacteria." Lastly, for non-public health product labels, PR Notice 2000-1 specifically allows stronger words than "protectant," such as "antimicrobial" and "preservative" as long as they are appropriately qualified (see PR Notice 2000-1, section II.B.4).

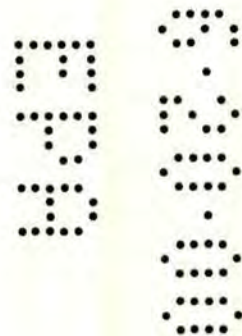
We hope and trust that this submittal satisfies all outstanding requirements for the registration of BST Protectant RTU 50. If, however, you should have any questions regarding the submittal or require additional information, please call.

Sincerely,



James S. Damico
President

Enclosures



TLANTZ
5563728
D256959

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 70871-0 PM 31 Action Code 187

10 Descriptor (Amend/Resubmissions only) _____

5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No 15 Child-resistant Packaging ☐ (C) Certification ☐ (S) Service Person

20 Registration Type: ☐ (1) Conditional ☐ (2) Unconditional ☐ (R) Non-residential Use Only ☐ (N) Not-Applicable

25 Proposed Classification: ☐ (R) Restricted ☐ (G) General 30 Final Classification: ☐ (R) Restricted ☐ (N) Not Classified

35 Date on Application: 03/18/99 40 EPA Received Date: 03/19/99 40 Date Received by PM: 04/13/99

Blue Date:
7/17/99

80 Method of Support: ☐ (1) Cite-All ☐ (6) Owner Submission ☐ (4) Not Applicable ☐ (7) Total Submission ☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL					
DEB					
NDEB					
TB					
EEB					
EFGB					

115 FINAL Response ACTION Code 13

120 Response

JUL 15 1999

75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

Product/Tx

NOTE TO THE JACKET

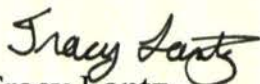
70871-U and 70871-G

7/22/99

Item no. 8 on label comments should have said: *our letter of 7/15/99*

“This product may be used on the following surfaces:”

Make this correction the next time this label comes in.


Tracy Lantz
Team 31

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BioShield Technologies, Inc.
4405 International Boulevard, Suite B109
Norcross, GA 30093

JUL 15 1999

ATTENTION: James S. Damico
Agent for BioShield

SUBJECT: BST Protectant 50
EPA File Symbol 70871-U
Your Application for Registration Dated: March 18, 1999

This is response to the application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to register 70871-U. This application is unacceptable.

Acute Toxicity

The data to support acute toxicity has been reviewed.

The acute toxicity regulatory profile for BST Protectant 50 is summarized in the table below.

Data Requirement	Means of Support	Tox. Category for 70871-U
Acute Oral Toxicity	cite study (MRID 403852-01)	IV
Acute Dermal Toxicity	cite study (MRID 403852-01)	III
Acute Inhalation Tox.	cite study (MRID 411578-03)	III
Primary Eye Irritation	submitted study (MRID 447898-01)	IV
Primary Dermal Irritation	cite study (MRID 403852-01)	III
Dermal Sensitization	cite study (MRID 421974-01)	Non-sensitizer

CONCURRENCES

SYMBOL	7510C						
SURNAME	J. L. Lutz						
DATE	7/15/99						

98

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PRODUCT LABELING

Based on the above acute toxicity profile, the required human-hazard and first-aid label statements in accordance with the *Label Review Manual* are given below.

Signal Word: CAUTION

Precautionary statements to appear under the heading HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

CAUTION. Harmful if inhaled or absorbed through skin. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Instructions to appear under the heading STATEMENT OF PRACTICAL TREATMENT (or FIRST AID):

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Data Compensation

Your application does not qualify for the Formulator's Exemption Statement since you are not purchasing a registered active ingredient. (You may not purchase an ingredient from yourself.) Submit a new Certification with Respect to Citation of Data Form and Data Matrix using the new forms as per PR Notice 98-5. Your Data Matrix must cite generic data for this active ingredient as well as all product specific data which has been submitted or cited to support this application for registration.

Confidential Statement of Formula

In the future, when submitting a Confidential Statement of Formula (CSF) for this product, when listing the source of the active ingredient, do not separate the active and inert ingredients in that source. For example, the total amount of 70871-2 in this product is [REDACTED] with the percent by weight equaling [REDACTED]. Then list the nominal concentration of the active ingredient when using this source on a separate line in section 13b (n=0.5).

Label Comments

1) As per the Registration Notice for 70871-2 dated 10/13/98, the term "protectant" is unacceptable for this product. Thus you must propose a new name for this product as well as

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

delete all references to the word "protectant" and the associated word "protection." Both of these terms appear numerous times throughout your proposed label. Refer to the label of 70871-2 for acceptable claims.

- 2) In order to use the term "long-lasting", this term must be defined. Does the treatment last for one month? One year?
- 3) Your label may not refer to "Germs" unless those claims are supported by efficacy data (which must be submitted, reviewed and accepted by the Agency) and your label lists the specific organism(s) against which your product is effective.
- 4) The phrase "Not Destroyed or Removed by Repeated Cleaning" must be qualified. How many cleanings may be performed without effecting the activity imparted by this product?
- 5) The claim "Removes Contaminants (That May Cause Allergies)" is inappropriate for this product. This product does not "remove contaminates", it inhibits the growth of bacteria and mildew. A claim against allergies is considered a public health claim for which efficacy data must be submitted, reviewed and accepted by the Agency.
- 6) Change the phrase "Eliminates Odors" to "Resists Development of Odors".
- 7) Your proposed label lists several sites which we have identified as "new uses" for this active ingredient. Any site for which this active ingredient has not previously been registered is considered a new use and includes the following: Patio Furniture, Canvas, Vinyl, Fiberglass, Wood, Plastic, Bath Mats, Pool Areas, Boats, Water Sport Equipment, Floor Mats, Concrete, Car/Truck Interiors, Wallets, Driveways, Decks, Painted Surfaces, and Recreational Vehicles. The following sites which do not agree with those listed on the label for 70871-2 are considered "new uses" for the product: Shower Stalls, Toilet Areas, Walls, Countertops (not including food-contact surfaces), Cabinets (not including food contact surfaces), Sinks, and Garbage Containers. Due to the fact that your label lists these "new uses" for the active ingredient, your revised label will go to science as a new use for this active ingredient for a determination as to whether any additional data is needed or if any additional risk is posed by these uses. This type of review would be quite lengthy and likely include additional label comments. Alternately, you may delete these uses which are not in agreement with the label for 70871-2 and apply to add these new uses at a later date if this product becomes registered. The present label does not contain enough information to be sent to science for review.

Your label must provide the following additional information regarding these sites:

- A. Many of these sites appear to be inappropriate for this type of product. For example, why would you use this product to treat a wall or a driveway? Explain your intentions in your cover letter.
- B. For each of the new sites listed above, identify the pest against which your product is treating.

CONCURRENCES							
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SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

C. Your label must specify the following: What toilet areas? What items made out of canvas? What items made out of vinyl, fiberglass, wood, and plastic? What type of upholstery? Fabrics made of which materials? Bath mats made of what? If you propose to keep the site "boats" you must identify exactly which areas of a boats may be treated with this product. Floor mats made of what types of materials? What items made of concrete? What areas of car/truck interiors do you propose to treat? Clothing, jackets and shoes/socks are all too board. Specify exactly what types of clothing and shoes are to be treated. What types of painted surfaces do you intent to treat with this product? A possible example would be painted and finished wood. Driveways and decks made of what types of materials? What areas associated with recreational vehicles do you propose to treat?

8) Under "Approved Uses" delete the phrase "Examples include but are not limited to:" Your label will be limited to only the sites which are listed on a label which has been accepted by the Agency. Broad statements such as "Examples include but are not limited to:" will not be allowed. The fourth page of your label includes the statement "Examples or areas and materials for use of Protectant:" which also will not be allowed. This statement must be specific such as the following example: "Surfaces on which this product may be used include:".

9) Is this product intended for homeowner use? If so the following information must be provided on this label in order for the Agency to continue its review of this product. Revise the "Directions for Use" to include the following information: list an application rate, the amount of product to apply per square foot, the appropriate dilution rate, how often to treat any particular area, explain what type of device should be used for application, provide mixing instructions, address exposure of children and pets to wet carpet and other areas which they are likely to contact, whether the surfaces should be allowed to air dry or be wiped dry.

Some of the uses on this label are inappropriate for treatment by a homeowner such as fire hose fabric, humidifier belts, polyurethane foam for packaging and cushioning in non-food contact applications, etc. Thus your label must list homeowner sites and directions separate from the sites and directions which are appropriate in a commercial establishment.

If this product is not intended for homeowner use then the following statement must be included on this label: **For Commercial and Industrial Use Only.**

10) On page three under "Approved Uses" delete the sites "building cleaning and building treatment."

11) On page three delete any references to "broad spectrum."

12) The claim "Provides residual activity against athletes foot fungus.....on the sock, durable for up to 10 repeated washings." is unacceptable. This claim is not on the accepted label of 70871-2 and may only be included on this label if data is submitted, reviewed, and accepted by the Agency which supports this claim.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

13) On page two of the collateral labeling the statement "Good durability-BST Protectant 50 imparts durable, residual, broad spectrum, biostatic activity to the surface of a wide variety of substrates." must be revised as follows "Good durability- (NEW PRODUCT NAME) imparts biostatic activity to the surface of a wide variety of substrates."

Revise your collateral labeling to agree with the comments made above on the label. Upon resubmission, the collateral labeling will be reviewed to determine whether it is in agreement with your revised label for this product.

This letter does not constitute registration and this product cannot be lawfully marketed until it is registered. The Agency obviously has numerous questions and concerns regarding this application. Your answers and label revisions may result in further concerns and comments on the part of the Agency. The agency reserves a full label review until the above issues have been addressed. Submit five (5) copies of the revised labels for review.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

7510C:T.Lantz:7/12/99:70871-U

CONCURRENCES

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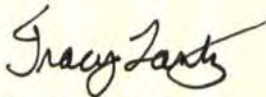
NOTE TO THE JACKET

70871-U and 70871-G

7/15/99

If these applications come back in and limit themselves to only the sites which are new uses for the product, then they will have to amend the label of 70871-2 and add those sites to that label in order to include them on either of these labels. (per conversation with Dennis Edwards)

In addition, I decided not to send the Tox reviews since BioShield has not offered compensation to cite these studies. They originally submitted waivers based on the fact that this data existed. Their Data Comp form says they are the original data submitters. There is NO Data Matrix. All that is included is a cover letter describing the studies they would like to cite. If they actually offer to pay compensation for these studies, then I would provide the reviews.



Tracy Lantz
Team 31

BST Protectant 50

MICROBIOSTATIC AGENT & PROTECTANT

Mold, Mildew, & Odor Protectant
Imparts Microbiostatic Properties
Long-Lasting Microbiostatic Protection
Long-Lasting Protection from Mold and Mildew
Provides a Durable and Invisible Microbiostatic Coating
Long-Lasting Protection from deterioration caused by Bacteria and Germs
Long-Lasting Odor Protection
Molecularly Bonds to Provide Lasting Protection
Molecularly Bonds to Remain Active on Surface
Not Destroyed or Removed by Repeated Cleaning
Unscented

Removes Contaminants (That may cause Allergies)
Use on Carpet and Upholstery to Protect from Odor Causing Bacteria, Mold, Mildew, Germs
Use on Carpet and Upholstery Protect from deterioration caused by Bacteria, Mold, Mildew, Germs
Eliminates Odors at the Source
Prevents Deterioration caused by Bacteria, Mold, Mildew, Fungi, Germs
Eliminates Odors
Long-Lasting protection
Provides Long-Lasting Protection
Provides Long-Lasting Protection by Forming and Invisible Barrier
Eliminates Odors at the Source
Imparts Residual, Long Lasting Microbiostatic Protection

Active Ingredient:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	0.5%
Inert Ingredients:	99.5%
TOTAL	
INGREDIENTS:	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

Lot No. _____ EPA EST. xxxxx-GA-xx

NET CONTENTS: 2, 4, 8, 16, 20, 22, 32 or 36 fluid oz.; 0.5, 1, 5, 55, 150, or 300 gal.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush with plenty of water. Call physician if irritation persists.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.
IF SWALLOWED: Call physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available, by administering syrup of ipecac. Do not give anything by mouth and do not induce vomiting.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through the skin. Avoid breathing vapors and mist. Causes moderate eye irritation. Avoid contact with eyes and skin. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE (Option 1)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

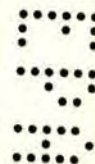
BST Protectant 50 is ready to use. For effective and lasting protection, wet PRE-CLEANED surface with diluted BST Protectant 50 thoroughly. Let stand several minutes and wipe dry with cloth or sponge. Let stand until dry, if spotting occurs, wipe with moist cloth or sponge. For sensitive surfaces (ie., fabric, suede, marble), apply protectant to small concealed area to test for staining and discoloration.

DIRECTIONS FOR USE (option 2)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

BST Protectant 50 is diluted at a ratio of (1:4) with one part BST Protectant 50 to four parts water. BST Protectant 50 is effective when diluted (1:4), especially when applied routinely.

For effective and lasting protection, wet PRE-CLEANED surface with diluted BST Protectant 50 thoroughly. Let stand several minutes and wipe dry with cloth or sponge. Let stand until dry, if spotting occurs, wipe with moist cloth or sponge. For sensitive surfaces (ie., fabric, suede, marble), apply protectant to small concealed area to test for staining and discoloration.



APPROVED USES

BST Protectant 50 is approved as a microbiostatic agent for use in laundry, carpet treatment, upholstery and drapery treatment, and building cleaning and building treatment.

BST Protectant 50 can be used to impart durable, residual, long-lasting, broad spectrum, microbiostatic protection to hard and soft surfaces.

Examples include but are not limited to:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towlettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; Provides residual activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up to 10 repeated washings.
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;

- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

BST Protectant 50 can be used to impart durable, residual, long-lasting broad spectrum, microbiostatic protection to substrates. Examples or areas and materials for use of Protectant:

- Patio Furniture
- Shower Curtains
- Shower Stalls
- Toilet Areas
- Canvas
- Vinyl
- Fiberglass
- Wood
- Plastic
- Upholstery
- Fabrics
- Indoor/Outdoor Carpet
- Throw Rugs
- Bath Mats
- Pool Areas
- Walls (indoor/outdoor)
- Boats
- Water Sport Equipment
- Floor Mats
- Concrete
- Countertops (not including food-contact surfaces)
- Car/Truck interiors
- Cabinets (not including food contact surfaces)
- Sinks
- Draperies
- Window treatments
- Wallets
- Garbage containers
- Clothing
- Jackets
- Shoes/Socks
- Driveways
- Decks
- Painted surfaces
- Recreational vehicles

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed. BST Protectant 50 has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS).
THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE
B109, NORCROSS, GEORGIA, 30093.

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to the seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

443

05.07.09

05.02.02

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COLLATERAL LABELING

- 6 -

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109
Norcross, GA 30093

Information About Microbiostatic Agents:

BST Protecant 50

U.S. Environmental Protection

Agency Registration Number

Type Silicone quaternary ammonium salt

Physical Form Low-viscosity liquid

Special Properties Surface bondability

Primary Uses ... As a microbiostatic agent for the treatment of hard and soft surfaces such as, laundry treatment, carpet treatment, upholstery and drapery treatment, and building cleaning and treatment to give a surface-durable residual, long-lasting microbiostatic treatment effective and active against a wide variety of fungi, mold, mildew, and algae.

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications*

Structure.....	$\begin{array}{c} \text{CH}_3 \\ \\ [(\text{CH}_3\text{O})_3\text{Si}(\text{CH}_2)_3\text{N}-\text{C}_{18}\text{H}_{37}]^+\text{Cl}^- \\ \\ \text{CH}_3 \end{array}$
Concentration.....	0.5%
Appearance.....	Colorless Liquid
Solubility.....	Miscible in all proportions* with water, ethanol, and methanol
Thermal Stability °C (°F).....	Stable to 30°C (86°F)

* Specification Writers: Please contact BioShield for information regarding specifications

DESCRIPTION

BST Protecant 50 is BioShield's designation for a water based solution containing the active ingredient 3-(trimethoxysilyl) propyloctadecyldimethyl ammonium chloride. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

BST Protecant 50 offers users the following features:

- Good durability— BST Protectant 50 imparts durable, residual, broad spectrum, biostatic activity to the surface of a wide variety of substrates.
- Broad Spectrum activity— Effective against fungi, algae, mold and mildew; Biostatic activity is exhibited on contact.
- Long-lasting activity— Active by leaving an invisible, protective bonded shield on surface.
- Increased efficiency—Through proper application, durable bacteriostatic, fungistatic, mildewstatic and algaestatic surfaces can be attained with a minimum amount of BST Protecant 50.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides freshness and combats deterioration caused by bacteria, fungi, and algae as a microbiostatic agent
- The microbiostatic agent remains invisibly bonded and active on most surfaces.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of an article by inhibiting the growth of bacteria and mildew.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the microbiostatic agent BST Protecant 50 are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. BST Protecant 50 inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. BST Protecant 50 forms a coating on a wide variety of substrates and its microbiostatic action is exhibited on contact.

APPROVED USES

The active ingredient in BST Protectant 50 is effective against fungi (including mold and mildew) and algae as a static agent.

BST Protectant 50 can be used for treatment of the following items or substrates to impart bacteriostatic/fungistatic activity:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- *Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);*
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

BST Protectant 50 can be used to impart durable, residual, long-lasting broad spectrum, microbiostatic protection to substrates. Examples of areas and materials for use of Protectant:

- Patio Furniture
- Shower Curtains
- Shower Stalls
- Toilet Areas
- Canvas
- Vinyl
- Fiberglass
- Wood
- Plastic
- Upholstery
- Fabrics
- Indoor/Outdoor Carpet
- Throw Rugs
- Bath Mats
- Pool Areas
- Walls (indoor/outdoor)
- Boats
- Water Sport Equipment
- Floor Mats
- Concrete
- Countertops (not including food-contact surfaces)
- Car/Truck interiors
- Cabinets (not including food contact surfaces)
- Sinks
- Draperies
- Window treatments
- Wallets
- Garbage containers
- Clothing
- Jackets
- Shoes/Socks
- Driveways
- Decks
- Painted surfaces
- Recreational vehicles

DIRECTIONS FOR USE (Option 1)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

BST Protectant 50 is ready to use. For effective and lasting protection, wet PRE-CLEANED surface with diluted BST Protectant 50 thoroughly. Let stand several minutes and wipe dry with cloth or sponge. Let stand until dry, if spotting occurs, wipe with moist cloth or sponge. For sensitive surfaces (ie., fabric, suede, marble), apply protectant to small concealed area to test for staining and discoloration.

DIRECTIONS FOR USE (option 2)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

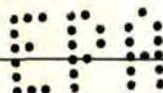
BST Protectant 50 is diluted at a ratio of (1:4) with one part BST Protectant 50 to four parts water. BST Protectant 50 is effective when diluted (1:4), especially when applied routinely.

For effective and lasting protection, wet PRE-CLEANED surface with diluted BST Protectant 50 thoroughly. Let stand several minutes and wipe dry with cloth or sponge. Let stand until dry, if spotting occurs, wipe with moist cloth or sponge. For sensitive surfaces (ie., fabric, suede, marble), apply protectant to small concealed area to test for staining and discoloration.

PRECAUTIONARY STATEMENTS

Hazard to Human and Domestic Animals

CAUTION: Harmful if inhaled or absorbed through the skin. Avoid breathing vapors and mist. Causes moderate eye irritation. Avoid contact with eyes and skin. Wash thoroughly with soap and water after handling.



ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed. BST Protectant 50 has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

REFERENCES

1. Hough, J.S. and Lyons, T.P. "Coupling of Enzymes Onto Microorganisms" *Nature*. London, 1972, 235: 389.
2. Johannsen, O.K., Stark, F.O., Vogel, G.E., and Fleischmann, R.M. "Evidence for Chemical Bond Formation at Silane Coupling Agent Interfaces." *J. Compos. Mater.*, 1967, 1:278-292.
3. Plueddemann, E.P. "Adhesion Through Silane Coupling Agents." *J. Adhesion*, 1970, 2:184-201.
4. Venter, J.C., Dixon, J.E., Maroko, P.R., and Kaplan, N.O. "Biologically Active Catecholamines Covalently Bound to Glass Beads." *Proc. Nat. Acad. Sci. (U.S.A.)*. 1972, 69:1141-1145.
5. Weetall, H.H. "Trypsin and Papain Covalently Coupling to Porous Glass." *Science*, 1969, 166:615-617.
6. Isquith, A.J., Abbott, E.A., and Walters, P.A. "Surface-Bonded Antimicrobial Activity of an Organosilicon Quaternary Ammonium Chloride." *Appl. Microbiol.*, 1972, 24:859-863.
7. Gettings, R.L. and Triplett, B.L. "A New Durable Antimicrobial Finish for Textiles." *AATCC Book of Papers—1978 Nat. Tech. Conf.*, 1978, 259-261.
8. Isquith, A.J. and McCallum, C.J. "Surface Kinetic Test Method for Determining Rate of Kill by an Antimicrobial Solid." *Appl. & Environ. Microbiol.*, 1978, 36:700-704.

DP BARCODE: D256959

CASE: 061998
SUBMISSION: S563728

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/07/99
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 187 RESB AmD-OC-MINOR CHG
CHEMICALS: 107401 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammon 0.5000%

ID#: 070871-U BST PROTECTANT 50
COMPANY: 070871 BIOSHIELD TECHNOLOGIES, INC
PRODUCT MANAGER: 31 VELMA NOBLE 703-308-6233 ROOM: CS1 6W18
PM TEAM REVIEWER: TRACY LANTZ 703-308-6415 ROOM: CS1 6W5
RECEIVED DATE: 03/19/99 DUE OUT DATE: 07/17/99

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 256959 EXPEDITE: Y DATE SENT: 04/14/99 DATE RET.: / /
CHEMICAL: 107401 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chlor
DP TYPE: 001

	CSF: Y		LABEL: Y	
ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 07/18/99	
DIV : AD	04/14/99	/ /	NEGOT DATE: / /	
BRAN: EASSB	07/01/99	/ /	PROJ DATE: / /	
SECT: CTT	07/01/99	/ /		
REVR : WPOWELL	07/01/99	/ /		
CONTR:	/ /	/ /		

* * * DATA REVIEW INSTRUCTIONS * * *

Submission is in response to Agency letter dated 1/13/98. They want to proceed w/ a registration. Please review the primary eye irritation study, MRID No. 447898-01. Original submission was submitted under the wrong registration number.

* * * DATA PACKAGE EVALUATION * * *

The data included here was originally submitted on 4/14/99 under 70871-A / D255207. This submission was deleted on 7/6/99 per Tracey's request.

The data for 70871-A was then included under 70871-U. The date will be reviewed under 70871-U / D256959.

Please note: the original received date on the bean is 3/19/99. The date sent was 4/14/99. The transfer on data was made on 7/1/99 and entered into PRATs on 7/6/99.

KP Hicks

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

07/13/99

MEMORANDUM

Subject: D256959
BST Protectant 50, Product No. 70871-U

From: Wallace Powell, Biologist
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

Thru: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Efficacy and Science Support Branch (ESSB)
Antimicrobials Division (7510C)

To: Velma Noble, Product Manager, Team 31
Tracy Lantz, Team Reviewer, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

BACKGROUND

The applicant, BioShield Technologies, Inc., has submitted (through its agent) a primary eye irritation study, MRID No. 447898-01. The study was submitted in support of product registration for BST Protectant 50, EPA File Symbol 70871-U. The active ingredient in the product is 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride (EPA code 107401), at 0.5% of the formulation by weight.

In support of the acute inhalation toxicity data requirement, BioShield has cited MRID 411578-03. For primary dermal irritation, BioShield has cited MRID 403852-01. Acute oral toxicity Category IV and acute dermal toxicity Category III were previously established for the product (refer to 1/13/98 EPA letter and its 1/13/98 review memo attachment).

DISCUSSION AND RECOMMENDATION

Acute Inhalation Toxicity. BioShield previously cited MRID 411578-03 (submitted in the past for EPA Reg. No. 64881-2, prior to its being transferred from Reg. No. 34292-2). In a 1/13/98 ESSB review for the subject product, the study was called unacceptable based on a cursory review, because the number and spacing of the dose concentrations were not adequate for the calculation of an LC_{50} . A Health Effects Division (HED) full review dated 1/5/90 called the study Supplementary (unacceptable but upgradable) and requested submittal of the purity of the test material and submittal of a rationale for the low test doses used. In a "Phase Four Review" dated 12/3/92 (from the reregistration file for Case No. 3148), it is noted that the registrant subsequently supplied information by Fax that allowed the study to be upgraded to Minimum. The study used two doses, 0.35 and 0.45 mg/L. There were no deaths at either dose. Although the 1/5/90 review placed the test material in Category II, the 0.45 mg/L dose is so close to the Category III boundary dose of 0.50 mg/L¹ that the test material most likely would have turned out to be in the Category III range had the study been conducted with a complete range of doses. Therefore, since the active ingredient was 72% (w/w) in the product tested, this argues in favor of assigning Category III to the subject product 70871-U, which contains the active ingredient at only 0.5% (w/w). The two products appear reasonably similar otherwise.

Primary Eye Irritation. The submitted study on the subject product is acceptable and places the test substance in Category IV. The test substance is substantially similar (and appears identical) to the subject product. The ESSB review of the study is attached to this memorandum.

Primary Dermal Irritation. As pointed out in the 1/13/98 ESSB review, the subject product 70871-U would appear similar to the product for which the cited study was submitted in the past (EPA Reg. No. 64881-2), except that the subject product is far less concentrated in terms of the active ingredient. Because the cited study indicates Category III, the subject product can also be assigned to Category III.

Dermal Sensitization. The cited study, MRID No. 421974-01, was cited in the applicant's previous submission. (It appears that the study was initially submitted in the past for EPA Reg. No. 64881-1 or -2; purity of active ingredient was 72%.) The study had been submitted as 'generic' data in the reregistration process. In the 1/13/98 ESSB review for the subject product (70871-U), based on a cursory review, the study was said to appear acceptable and could be bridged to support the subject product on a tentative basis. A formal review was (and still is) pending in the reregistration process. Since that time, a 2/7/92 Agency review was found which calls the study acceptable with a non-sensitizing response. In the unlikely

¹ Category III begins at $LC_{50} > 0.50$ mg/L

event that the pending reregistration review disagrees with the 2/7/92 review, a resulting requirement will be given under the reregistration program.

The acute toxicity regulatory profile for BST Protectant 50 is summarized in the table below.

Data Requirement	Means of Support	Tox. Category for 70871-U
Acute Oral Toxicity	previously cited study (MRID 403852-01)	IV
Acute Dermal Toxicity	previously cited study (MRID 403852-01)	III
Acute Inhalation Tox.	cited study (MRID 411578-03)	III
Primary Eye Irritation	submitted study (MRID 447898-01)	IV
Primary Dermal Irritation	previously cited study (MRID 403852-01)	III
Dermal Sensitization	previously cited study (MRID 421974-01)	Non-sensitizer

PRODUCT LABELING

Based on the above acute toxicity profile, the required human-hazard and first-aid label statements in accordance with the *Label Review Manual* are given below.

Signal Word: CAUTION

Precautionary statements to appear under the heading HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

CAUTION. Harmful if inhaled or absorbed through skin. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Instructions to appear under the heading STATEMENT OF PRACTICAL TREATMENT (or FIRST AID):

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4)

Reviewer: W. Powell
Product No.: 70871-U
DP Barcode: D256959
MRID No.: 447898-01
Study No.: 4842-98
Report Date: 01/21/99 (study completion date)
Author: Janice O. Kuhn

Conclusion:

Toxicity Category: IV
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Deficiencies: None noted

Testing Facility: Stillmeadow, Inc. (12852 Park One Drive, Sugar Land, TX 77478)

Test Material: AM500, Lot # B039830A-2 (Dilute to 0.5% a.i. from 5% a.i.), a yellow gel; 5.04% total quaternary ammonium chloride; dilution material was [REDACTED] water. (BioShield's 3/18/99 Transmittal Document calls it a "0.5% dilution of BioShield product AM500.")

Test Animal: Rabbit, albino, New Zealand White; 3 per sex
Age: 13 to 16 weeks
Weight: Males 2000-2350 g; females 2200-3000 g
Source: Ray Nichols Rabbitry - Lumberton, TX

Test Method: 0.1 mL of the diluted test material was instilled into the conjunctival sac of one eye of each of three rabbits per sex that were pre-screened for eye abnormalities. The eyelids were held together for 1 second. The other eye was untreated and served as a control. All treated eyes were washed with de-ionized water following the 24-hour observation. Ocular reactions were recorded at approximately 1, 24, 48, and 72 hours after dosing, and graded in accordance with the Draize scale and EPA guidelines. Fluorescein ophthalmic solution was employed at the 24-hour observation. Where corneal staining resulted, this solution was re-applied at each consecutive observation time until retention of staining no longer occurred.

Results and Discussion: No 'positive' effects were observed. No effects at all were observed at 48 hours or later. No fluorescein staining was observed. The study was terminated after the 48-hour observation. These results place the test material in Category IV for primary eye irritation (i.e., minimal effects, clearing in less than 24 hours).

Commercial/financial information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

07/13/99

MEMORANDUM

Subject: D256959
BST Protectant 50, Product No. 70871-U

From: Wallace Powell, Biologist
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

Thru: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Efficacy and Science Support Branch (ESSB)
Antimicrobials Division (7510C)

To: Velma Noble, Product Manager, Team 31
Tracy Lantz, Team Reviewer, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

BACKGROUND

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DISCUSSION AND RECOMMENDATION

Acute Inhalation Toxicity. BioShield previously cited MRID 411578-03 (submitted in the past for EPA Reg. No. 64881-2, prior to its being transferred from Reg. No. 34292-2). In a 1/13/98 ESSB review for the subject product, the study was called unacceptable based on a cursory review, because the number and spacing of the dose concentrations were not adequate for the calculation of an LC_{50} . A Health Effects Division (HED) full review dated 1/5/90 called the study Supplementary (unacceptable but upgradable) and requested submittal of the purity of the test material and submittal of a rationale for the low test doses used. In a "Phase Four Review" dated 12/3/92 (from the reregistration file for Case No. 3148), it is noted that the registrant subsequently supplied information by Fax that allowed the study to be upgraded to Minimum. The study used two doses, 0.35 and 0.45 mg/L. There were no deaths at either dose. Although the 1/5/90 review placed the test material in Category II, the 0.45 mg/L dose is so close to the Category III boundary dose of 0.50 mg/L¹ that the test material most likely would have turned out to be in the Category III range had the study been conducted with a complete range of doses. Therefore, since the active ingredient was 72% (w/w) in the product tested, this argues in favor of assigning Category III to the subject product 70871-U, which contains the active ingredient at only 0.5% (w/w). The two products appear reasonably similar otherwise.

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PRODUCT LABELING

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Precautionary statements to appear under the heading HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

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IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

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DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4)

Reviewer: W. Powell
Product No.: 70871-U
DP Barcode: D256959
MRID No.: 447898-01
Study No.: 4842-98
Report Date: 01/21/99 (study completion date)
Author: Janice O. Kuhn

Conclusion:

Toxicity Category: IV
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Deficiencies: None noted

Testing Facility: Stillmeadow, Inc. (12852 Park One Drive, Sugar Land, TX 77478)

Test Material: AM500, Lot # B039830A-2 (Dilute to 0.5% a.i. from 5% a.i.), a yellow gel; 5.04% total quaternary ammonium chloride; dilution material was [REDACTED] water. (BioShield's 3/18/99 Transmittal Document calls it a "0.5% dilution of BioShield product AM500.")

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Commercial/financial information may be entitled to confidential treatment

March 18, 1999

Ms. Velma Noble
Product Manager 31
Antimicrobials Division (7510W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Re: BST Protectant 50 (EPA File Symbol No. 70871-U)

Dear Ms. Noble:

In response to your letter of January 13, 1998 to BioShield Technologies, Inc., enclosed please find the following materials:

1. Five copies of the revised product label and collateral label. The collateral label was revised in accordance with your request (i.e., the statement "contains no phenols, tin, heavy metals..." was removed). Additionally, all labeling was revised for consistency and compliance with various changes requested by the EPA on the labels for BioShield's recently-registered AM 500 and AM 500I products (e.g., antimicrobial claims were deleted). As the antimicrobial claims have been deleted, it is believed that the Agency no longer requires the submittal of the efficacy data requested in your letter.
2. Acute eye irritation study. The EPA requested the submittal of new acute inhalation, eye irritation, and dermal irritation studies. BioShield conducted a new guideline- and GLP-compliant eye irritation study (enclosed); however, we wish to rely on two studies already on file with EPA to support the inhalation and dermal irritation requirements:

MRID # 41157803 (Acute Inhalation): This study was originally rejected by EPA as unsupportive of AM 500, AM 500I, and BioShield's protectant products (including BST Protectant 50). However, upon re-evaluation, the Agency accepted the study to support the AM 500 and AM 500I registrations. As BST Protectant 50 is simply a water dilution of the relatively dilute AM 500 products, we feel the cited acute inhalation study is applicable to this product.

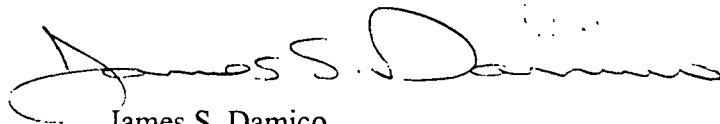
MRID # 40385201 (Acute Dermal Irritation): BioShield does not wish to rely on two studies referenced in EPA's January 1998 review (MRID # 93218047 and 42456513) as these studies were apparently conducted using a test material that was not

Damico to Noble
March 18, 1999
p. 2

sufficiently similar to BST Protectant 50. Instead, we wish to rely upon the study utilized by EPA to satisfy the dermal irritation requirements for the AM 500 products (MRID # 40385201). Again, because BST Protectant 50 is simply a water dilution of the AM 500 products, we feel the cited dermal irritation study is applicable to this product. It is highly unlikely that additional animal testing will change the signal word, precautionary statements, or first aid statements on the product label.

We believe this submittal will satisfy the EPA's outstanding issues relative to the registration of BST Protectant 50. If you should have any questions regarding the enclosed materials or this letter, please call.

Sincerely,

A handwritten signature in dark ink, appearing to read "James S. Damico". The signature is fluid and cursive, with a large initial "J" and "D".

James S. Damico
President

Enclosures

TRANSMITTAL DOCUMENT

Submitter

BioShield Technologies, Inc.
4405 International Blvd., Suite B109
Norcross, GA 30093

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

* SciReg, Inc. is the authorized agent for BioShield Technologies, Inc.

Regulatory action in support of which this package is submitted

Response to EPA letter dated January 13, 1998; new product registration
(BST Protectant 50; EPA File Symbol 70871-U)

Transmittal Date

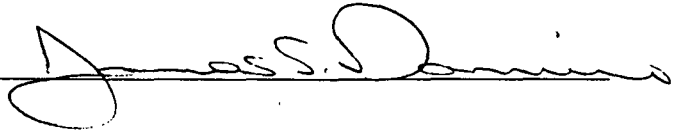
March 18, 1999

Contents

Vol. 1 Administrative Materials

Vol. 2 Primary Eye Irritation Study in Rabbits (0.5% dilution of BioShield product
44789801 AM 500) (Guideline 81-4; OPPTS 870.2400)

Company Official: James S. Damico



Company Name: SciReg, Inc.

Company Contact: James S. Damico (703) 494-6500

STILLMEADOW

INCORPORATED

VOLUME 2 OF 2 OF SUBMISSION

AM500 Batch # B039830A-2
(Dilute to 0.5% a.i. from 5% a.i.)

FINAL REPORT

PRIMARY EYE IRRITATION STUDY IN RABBITS

EPA FIFRA NO. 81-4 / OPPTS NO. 870.2400

AUTHOR:

Janice O. Kuhn, Ph.D., D.A.B.T.

STUDY INITIATION DATE: December 17, 1998

STUDY COMPLETION DATE: January 21, 1999

CONDUCTED BY:

STILLMEADOW, Inc.
12852 Park One Drive
Sugar Land, TX 77478

LABORATORY STUDY NUMBER:

4842-98

VOLUME 1 OF 1 OF STUDY

PAGE 1 OF 17

SUBMITTED TO:

BioShield Technologies, Inc.
4405 International Blvd., Suite B109
Norcross, GA 30093

March 18, 1999

Ms. Velma Noble
Product Manager 31
Antimicrobials Division (7510W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Re: BST Protectant 50 (EPA File Symbol No. 70871-U)

Dear Ms. Noble:

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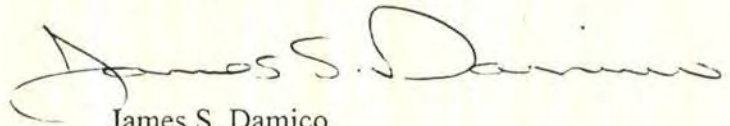
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Damico to Noble
March 18, 1999
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President

Enclosures

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Submitter

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Regulatory action in support of which this package is submitted

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(BST Protectant 50; EPA File Symbol 70871-U)

Transmittal Date

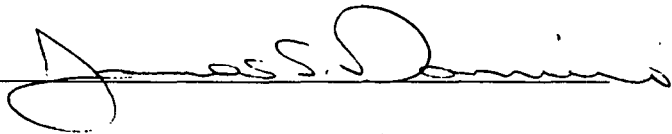
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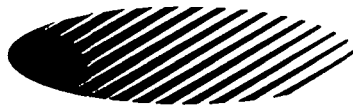
Vol. 2 Primary Eye Irritation Study in Rabbits (0.5% dilution of BioShield product
44789801 AM 500) (Guideline 81-4; OPPTS 870.2400)

Company Official: James S. Damico



Company Name: SciReg, Inc.

Company Contact: James S. Damico (703) 494-6500



BioShieldTM
BioShield Technologies Inc.

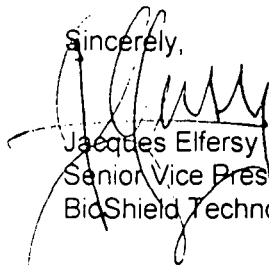
January 27, 1999

Mr. Frank Sanders
Director, Antimicrobials Division (7510W)
Office of Pesticide Programs
US Environmental Protection Agency
401M Street
Washington, DC 20460

Dear Mr. Sanders:

BioShield Technologies, Inc. hereby authorizes SciReg Inc., to act as its agent on all matters involving pesticide registrations.

Sincerely,


Jacques Elfersy
Senior Vice President
BioShield Technologies, Inc.

SciReg

Inc.

Inc.

SciReg

Inc.



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70871-U	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BST Protectant 50	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) BioShield Technologies, Inc. 4405 International Blvd., Suite B109 Norcross, GA 30093 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 1/31/98	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label revisions and submittal of additional acute toxicity data

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title President, SciReg, Inc. *Agent	
4. Typed Name James S. Damico	5. Date 3/18/99	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Bioshield Technologies, Inc.
4405 International, Suite B109
Norcross, GA 30093

JAN 13 1998

Subject: BST Protectant 50
EPA File Symbol No. 70871-U
Your Submission Dated September 12, 1997

Attn: Blane Dahl
Registration Manager

The application for registration of the subject product is not acceptable. Required materials as specified below must be submitted before processing of the application can be completed.

Product Chemistry

The Confidential Statement of Formula (CSF) dated September 12, 1997 is in compliance with PR Notice 91-2, it agrees with the label and is acceptable. Please submit one year Storage and Stability data to support claim "Disinfects up to one year".

The claim "Contains no phenols, tin, heavy metals, lead, mercury or formaldehyde" is not acceptable and must be deleted. All other claims will be re-evaluated when additional data is forwarded to the Agency.

Efficacy

Data submitted is insufficient. Agency need appropriate data to support the label claims. Please send in sufficient material to be re-evaluated.

Toxicity Review

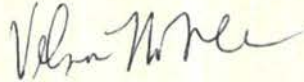
Please refer to the Attachment entitled "Memorandum" for comments.

Because of the importance of your application, we would like to have your reply within seventy-five (75) days. If you need additional time to reply or if you have any questions concerning the comments in this letter, you may contact Zenobia Jones at (703) 308-6198.

CONCURRENCES

SYMBOL	7510W						
SURNAME	Z. Jones						
DATE	1-12-98						

Sincerely,

A handwritten signature in dark ink, appearing to read 'Velma Noble', with a stylized, cursive script.

Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 13 1998

MEMORANDUM

Subject: BST Protectant Concentrate C15
EPA File Symbol 70871-G
Data Package D239768

BST Protectant 50
EPA File Symbol 70871-U
Data Package D239765

BST Protectant 75
EPA File Symbol 70871-L
Data Package D239760

From: Wallace Powell, Biologist *Wallace Powell*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

Thru: Laura E. Morris, Team Leader *Laura E. Morris*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

Norman Cook, Chief *my case 01/13/98*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

To: Velma Noble, Product Manager, Team 31
Zenobia Jones, Team Reviewer, Team 31
Registration Branch I
Antimicrobials Division

BACKGROUND

The applicant, BioShield Technologies, Inc. (as represented by Jellinek, Schwartz & Connolly, Inc.), has applied for registration of BST Protectant Concentrate C15, BST Protectant 50, and BST Protectant 75, three manufacturing-use products proposed for incorporation into anti-microbial products that are

used in cleaning products, textile and building treatment products, and a variety of manufactured items. The applicant has submitted a request for waivers of all product acute toxicity testing, and has cited several studies to show that existing data are sufficient to support registration.

DISCUSSION

According to a December 4, 1997 EPA memorandum from Timothy McMahon to Velma Noble, the following data is available for the active ingredient contained in these products. The memorandum notes that these tests were conducted on a 50% formulation.

<u>Study Type</u>	<u>MRID No.</u>	<u>Tox. Category</u>
Acute Oral Toxicity	403852-01	IV
Acute Dermal Toxicity	403852-01	III
Primary Eye Irritation	403852-01	I
Primary Dermal Irritation	403852-01	III

The subject products are water dilutions of a product resembling the product for which the studies cited in this memorandum were submitted. The dilution factors are rather large.

In support of registration of the subject products, the applicant has cited the above MRID 403852-01 and several additional studies also: 424565-11 (acute oral toxicity), 432199-01 (acute dermal toxicity), 411578-03 (acute inhalation toxicity), 932180-47 and 424565-13 (primary dermal irritation), and 421974-01 (dermal sensitization). Of these, according to our records, the acute oral toxicity study, MRID 424565-11, has been reviewed previously with a Toxicity Category IV result ($LD_{50} = 12.27$ g/kg), which is in agreement with the result in the list above. Because this is the Category of lowest toxicity, Category IV can be assigned to the subject products.

The acute dermal toxicity study with MRID No. 432199-01 is also not being reviewed for this memorandum. The study listed above with MRID No. 403852-01 was assigned Category III for acute dermal toxicity, and this Category can be assigned to the subject products for labeling purposes.

Based on a cursory review of the acute inhalation study, MRID No. 411578-03, the number and spacing of the dose concentrations were not appropriate for the calculation of an LC_{50} . Two dose concentrations were used (both within the Toxicity Category II

range). There was no third concentration, and there was no mortality which could be used for calculating an LC_{50} . The study is therefore not acceptable. An acceptable acute inhalation study is required, as conducted on the subject product formulations, as represented by BST Protectant Concentrate C15 (since its concentration is the highest of the three products).

As for primary eye irritation, Toxicity Category I is listed above for the concentrated material, but it is not known what Toxicity Category would result from the dilution represented by the subject products. Therefore an acceptable eye irritation study is required, as conducted on the subject product formulation. To reflect the source [REDACTED] material's Category I rating for eye irritation in the BioShield products may result in a significant overstatement of the hazard.

As for the primary dermal irritation studies with MRID Nos. 932180-47 and 424565-13, based on a cursory review of the studies it was noticed that individual animal data was not included, and observations ended at 72 hours in spite of the presence of significant irritation. The two studies suggest a Toxicity Category of I or II for primary dermal irritation. This is not in agreement with the Category III indicated for the MRID 403852-01 study listed above. Thus, the dermal irritation assessment is inconclusive, and a study is required for the diluted material.

The cited dermal sensitization study, MRID No. 421974-01, appears acceptable based on cursory review, indicating no sensitization response for the concentrated material. Therefore, the study is applicable to the subject product as well, acceptable on a tentative basis, until a complete review is conducted in the reregistration process. (It is this reviewer's intention to provide a review report well prior to that time.)

CONCLUSION

As per the foregoing discussion, the following Toxicity Categories can be assigned to the subject product for purposes of determining appropriate precautionary labeling.

Note that if the outcomes of the evaluations as a part of the Reregistration process (which are not yet completed) differ from these Toxicity Categories listed below, new data will be required.

<u>Acute Effect</u>	<u>Category</u>
Acute Oral Toxicity	IV
Acute Dermal Toxicity	III (assigned)
Acute Inhalation Toxicity	Study is required
Primary Eye Irritation	Study is required
Primary Dermal Irritation	Study is required
Dermal Sensitization	Non-sensitizer (tentative)

The precautionary labeling requirements for the subject product will be determined once the acute toxicity data requirements have been fulfilled.

FOPA 120 days

DP BARCODE: D239763

CASE: 061998
SUBMISSION: S531440

DATA PACKAGE RECORD
BEAN SHEET

DATE: 10/09/97
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 186 AmD-OC-MINOR CHANGE
CHEMICALS: 107401 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammon 0.5000%

ID#: 070871-U BST PROTECTANT 50
COMPANY: 070871 BIOSHIELD TECHNOLOGIES, INC
PRODUCT MANAGER: 31 VELMA NOBLE 703-305-7441 ROOM: CM2 268
PM TEAM REVIEWER: ZENOBIA JONES 703-308-6198 ROOM: CS1
RECEIVED DATE: 09/15/97 DUE OUT DATE: 01/13/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 239763 EXPEDITE: N DATE SENT: 10/07/97 DATE RET.: / /
CHEMICAL: 107401 3-(Trimethoxysilyl)propyl dimethyl octadecyl ammonium chlor
DP TYPE: 001

CSF: Y

LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 01/10/98
DIV : AD	9/15/97	/ /	NEGOT DATE: / /
BRAN: RASSB	10/10/97	/ /	PROJ DATE: / /
SECT: RASSB3	/ /	/ /	
REVR : <i>Sharnin</i>	10/17/97	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Laura, please review this submitted data for CSF amendments.
Thank You!

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
239761	RASSB/RASSB2	10/07/97	01/10/98	Y	N	Y
239765	RASSB/RASSB3	10/07/97	01/10/98	Y	N	Y



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Date Completed: Nov. 28, 1997

SUBJECT: PRODUCT CHEMISTRY REVIEW OF END-USE PRODUCT
BST PROTECTANT 50

To: Velma Noble, Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510W)

From: A. Najm Shamim, Chemist *AShamim*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

Thru: Laura Morris, Team Leader, Team-3 *HCont for 12/22/97*
Risk Assessment and Science Support Branch
Antimicrobials Division (7510W)

DP BARCODE No: D239763

SUBMISSION No: S531440

REG/FILE SYMBOL: 70871

CASE/TYPE: 061998/REGISTRATION

CASNo: 27668-52-6

EPA MRID Nos: 443762-01, 443762,02
443762-03

CHEMICAL NAME: 3-(TRIMETHOXYSILYL)PROPYL DIMETHYL OCTADECYL
AMMONIUM CHLORIDE (0.500%)

CLASS OF COMPOUND: QUAT

DATA SUBMITTER: 070871: BIOSHIELD TECHNOLOGIES, INC.

EPA RECEIVED DATE: 09/15/97

Please find the Product Chemistry Review of BST PROTECTANT 50

INTRODUCTION:

The submission by the applicant includes: product chemistry data, product 's CSF about the basic formulation dated 09/19/97 and a label (EPA received date: 09/15/97). The applicant seeks registration for the end-use product (EP) under FIFRA Section 3.

FINDINGS:

1. The source AI is not registered; however, data on AI was submitted 5/14/97.
2. The CAS # of the AI was incorrectly reported as 27668-52-0; the correct CAS # is :27668-52-6.
3. The product is formed by a non-integrated formulation system: no chemical reaction was reported to have taken place, as claimed by the applicant.
- ✓4. The submitted product chemistry data is adequate and support the registration requirements for this product.
5. Analytical Method for Enforcement of Limits of the AI (Springborn Laboratories Protocol # 102196/830:6317/Bioshield) were included with the submission; it was reviewed and found adequate. MRID#: 443762-02
6. The ingredient statement, the physical/chemical hazard statement and the storage and disposal statement cited on product label, EPA received 9/15/97, satisfy 40 CFR §156.10.
- ✓7. The submitted product's CSF's basic formulation dated 9/12/97 are adequate and satisfy the requirement of PR-Nitice 91-2 on nominal concentrations.
8. Description of Formulation Process were included in the submission: MRID#: 443762-01
9. Product chemistry data were included in the submission and were found adequate in support of registration of this end-use product. MRID#: 443762-03

CONCLUSIONS:

1. Pending registration of the AI { 3-(trimethoxy silyl)propyl dimethyl octadecyl ammonium chloride}, we will have no objection to register this product.
- ✓2. The applicant has satisfied the product chemistry for a Section 3 FIFRA registration

DETAILED CONSIDERATIONS

REVIEW OF PRODUCT CHEMISTRY DATA:

Group A: Series 830-Product Identity, Composition and Analysis.

(40 CFR 155, 160, 162, 167, 175 and 180)

830-1550 (61-1). Product Identity & Disclosure of Ingredients: MRID#: 443762-01

This product was formulated using non-registered technical grade of active ingredient with no intended chemical reaction, a process also known as non-integrated formulation system.. No reaction or production of new ingredients was reported by the applicant. Data on the TGAI was recently submitted (5/15/97) and is under review.

830-1600 (61-2a) Description of Materials Used to Produce the Product:MRID#: 443762-01

Refer to Confidential Appendix A

830-1650 (61-2b) Description of Formulation Process:MRID#: 443762-01

Refer to Confidential Appendix A

830-1670 (61-3) Discussion of Formation of Impurities:MRID#: 443762-01

Refer to Confidential Appendix A

830-1700 (62-1) Preliminary Analysis:

Refer to Confidential Appendix A

830-1750 (62-2) Certified Limits:

Refer to Confidential Appendix A

830-1800 (62-3) Enforcement Analytical Method: MRID#: 443762-02

The enforcement method, developed at Springborn Laboratories: protocol #: 102196/830.6317/Bioshield, can be used to analyze Quaternary Ammonium Chloride(QUAT) for the TGAI in the technical or formulated product between 50 ppm to 100% concentrations without differentiation of chain length distribution.

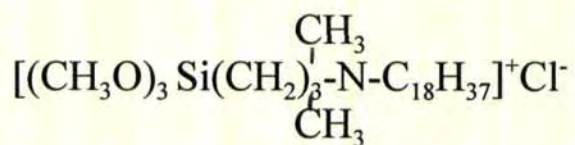
Group B: Series 830-Physical and Chemical Properties (40CFR § 158.190):MRID#:443762-03

GUIDELINE REFERENCE #/TITLE VALUE OR QUALITATIVE DESCRIPTION/
METHOD(s) USED WHERE APPLICABLE
AND REFERENCES

-6302	Color	Colorless
-6303	Physical State	Liquid
-6304	Odor	Odorless
-6314	Oxidation/Reduction Incompatibility	No oxidizing or reducing potential exists

-6315	Flammability/Flame Extension	N/A
-6316	Explosibility	Does not contain explosive materials
-6317	Storage Stability	N/A
-6319	Miscibility	N/A
-6320	Corrosion Characteristics	Non-Corrosive to the containers
-6321	Dielectric Breakdown Voltage	N/A
-63-7000	pH	5.28
-63-7100	Viscosity	<85.5 mPa.s
-63-7300	Density/Rel. Density/ Bulk Density	0.984 g/ml

Structure:



CONFIDENTIAL APPENDIX A

830-1600(61-2a)
the Product:

Description of Materials Used to Produce

The raw materials are listed on Product's CSF

830-1600(62-2b)

Description of Formulation Process:

The product is formulated by mixing the raw materials with no intended chemical reactions (it is a non-integrated system)

830-1670(61-3)

Discussion of Formation of Impurities

The applicants claim that no impurities $\geq 0.10\%$ by weight were known to form during formulation or storage as no chemical reaction takes place.

830-1700 (62-1)

Preliminary Analysis:

Not applicable for non-integrated systems.

830-1750 (62-2)

Certified Limits:

The applicant reported that certified limits of the active and the inert were established according to the standard limits required by 40 CFR § 158.175(b)(2). THE LIMITS ARE INDICATED ON PRODUCT'S CSF.

Jellinek, Schwartz & Connolly, Inc.

1525 Wilson Boulevard, Suite 600
Arlington, VA 22209
(703) 527-1670 • Fax: (703) 527-5477



Hand Delivered

Consultants in Environmental Science, Policy & Management

September 12, 1997

443762-00

Ms. Velma Noble (Acting PM 31)
Regulatory Management Branch I
Antimicrobials Division (H7505W)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Document Processing Desk
Room 266A, Crystal Mall 2
Arlington, VA 22202

Re: Application for Pesticide Registration
BST Protectant 50

Dear Ms. Noble:

On behalf of BioShield Technologies, Inc. (BioShield; 4405 International Boulevard, Suite B109, Norcross, Georgia, 30093; EPA Company Number 70871), we are submitting an application for pesticide registration for the end use product BST Protectant 50 (containing the active ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride [CAS# 27668-52-0]).

The source of the active ingredient in the proposed product is BioShield AM 500 I (EPA File Symbol 70871-E, Application for Registration submitted to the Agency on May 14, 1997). A copy of the label for this product is included in Volume I of this submission. Thus, BioShield is claiming a formulator's exemption, and no data on 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride technical grade active ingredient (TGAI) are included in this submission.

MEMBERS OF THE JSC GROUP OF COMPANIES:

Jellinek, Schwartz & Connolly, Inc. • Arlington, VA 22209 USA • (703) 527-1670 • Fax (703) 527-5477
JSC International Ltd. • Harrogate, North Yorkshire HG1 5QY • UK • (1423) 520245 • Fax (1423) 520297
Steiner, Inc. • Bryan, TX 77802 USA • (409) 846-5175 • Fax (409) 846-2671
JSC Specialty • Denver, CO 80202 USA • (303) 623-3100 • Fax (303) 623-3130

This application package is formatted in accordance with PR Notice 86-5 and contains the following required information to support the registration of BST Protectant 50:

VOLUME#	TITLE
I Administrative Material BST Protectant 50	Transmittal Document (this letter); Application for Registration (EPA Form 8570-1); CSF for BST Protectant 50 (EPA Form 8570-4); Formulator's Exemption Statement (EPA Form 8570-27); Certification With Respect to Citation of Data Form (EPA Form 8570-29); Data Matrix; Material Safety Data Sheet; Proposed Draft Labeling for BST Protectant 50 (5 copies); and BioShield AM 500 I labeling (1 copy).

Three copies of the following data and information are being submitted:

VOLUME#	GUIDELINE #	MRID	TITLE
II	Series 61	44376201	Product Identity and Composition (61-1); Description of Beginning Materials and the Manufacturing Process (61-2); and Discussion of Formation of Impurities (61-3)
III	Series 62	44376202	Certification of Limits (62-2); and Analytical Method for Enforcement of Limits (62-3)
IV	63-2, 63-3, 63-4, 63-7, 63-12, 63-18	44376203	Product Chemistry Studies (Color, Physical State, Odor, Density, pH, Viscosity)
V	Series 81	Admin	Waiver Request of Requirement for Further Testing for BST Protectant 50

BioShield will address shortly the following data requirements for BST Protectant 50: preliminary five batch analysis (EPA Guideline # 62-1), storage stability (EPA Guideline # 63-17), corrosion characteristics (EPA Guideline # 63-20), and efficacy (as required to support the proposed label claims).

If you have any questions about this application, please contact me at (703) 312-8531 or Kimberly Lowe at (703) 312-8539.

Sincerely,



Blane Dahl
Registration Manager
Jellinek, Schwartz & Connolly, Inc.
Authorized Representative of
BioShield Technologies, Inc.

Enclosures

c: Joachim Berkner, BioShield Technologies, Inc.

United States Environmental Protection Agency
Washington, DC 20460**Formulator's Exemption Statement**

(40 CFR 152.85)

Applicant's Name and Address BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093	EPA File Symbol/Registration Number 70871-U
	Product Name BST Protectant 50
	Date of Confidential Statement of Formula (EPA Form 8570-4) September 12, 1997

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

3- (trimethoxysilyl) propyldimethyloctadecyl ammonium chloride
 [CAS# 27668-52-0]

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

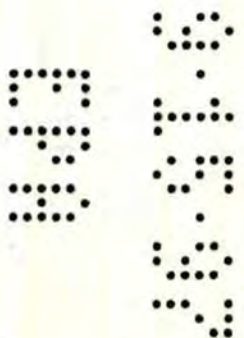
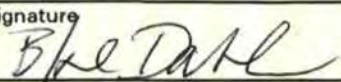
(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
3- (trimethoxysilyl) propyldimethyloctadecyl ammonium chloride [CAS# 27668-52-0]	BST Protectant 50 BioShield AM 500 I	70871-E
		
Signature 	Name and Title Blane Dahl, JSC, Auth. Rep. of BioShield Technologies, Inc.	Date Sept. 12, 1997

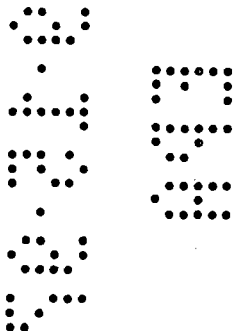
Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Chief, Information Policy Branch, PM-223
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503



United States Environmental Protection Agency
Washington, DC 20460**Formulator's Exemption Statement**

(40 CFR 152.85)

Applicant's Name and Address BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093	EPA File Symbol/Registration Number 70871-U
	Product Name BST Protectant 50
	Date of Confidential Statement of Formula (EPA Form 8570-4) September 12, 1997

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

3- (trimethoxysilyl) propyldimethyloctadecyl ammonium chloride
[CAS# 27668-52-0]

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient, which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

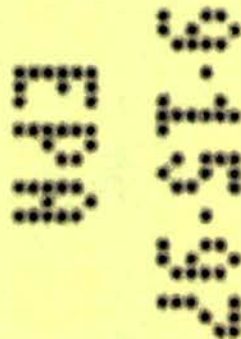
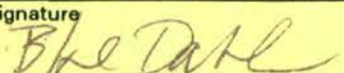
(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
3- (trimethoxysilyl) propyldimethyloctadecyl ammonium chloride [CAS# 27668-52-0]	BST Protectant 50 BioShield AM 500 I	70871-E
		
Signature 	Name and Title Blane Dahl, JSC, Auth. Rep. of BioShield Technologies, Inc.	Date Sept. 12, 1997

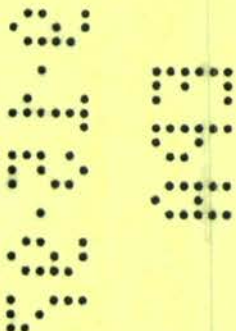
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The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Chief, Information Policy Branch, PM-223
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

and to

Office of Management and Budget
Paperwork Reduction Project (2070-0060)
Washington, DC 20503





United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 05-31-95

Certification with Respect to Citation of Data

Applicants Name and Address

BioShield Technologies, Inc.
4405 International Boulevard, Suite B109
Norcross, GA 30093

EPA File Symbol/Registration Number

70871-U

Product Name

BST Protectant 50

Date of Application

September 12, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

☐ I am the original submitter*; or

☐ I have obtained the written permission of the original submitter for _____, which is
(insert name of chemical)
_____ (for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

a. ☒ I am the original data submitter*; or

☐ I have obtained the written permission of the original data submitter for _____, which is
(insert name of chemical)
_____ (for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*; or

b. ☐ I have notified in writing the companies _____ for _____ that
(insert names of companies) (insert name of chemical)

have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all
method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)
Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
that have submitted the studies which I have cited (Selective method*).

4. ☐ I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature

Blane Dahl

Name and Title

Blane Dahl, Jellinek, Schwartz & Connolly
Auth. Rep. of BioShield Technologies, Inc.

Date

9/12/97

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature

Name and Title

Date

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503, marked "Attention Desk Officer for EPA."





Certification with Respect to Citation of Data

Applicants Name and Address

BioShield Technologies, Inc.
4405 International Boulevard, Suite B109
Norcross, GA 30093

EPA File Symbol/Registration Number

70871-U

Product Name

BST Protectant 50

Date of Application

September 12, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

☐ I am the original submitter*; or

☐ I have obtained the written permission of the original submitter for _____, which is
(insert name of chemical)
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with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

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have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

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that have submitted the studies which I have cited (Selective method*).

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* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature

Blane Dahl

Name and Title

Blane Dahl, Jellinek, Schwartz & Connolly
Auth. Rep. of BioShield Technologies, Inc.

Date

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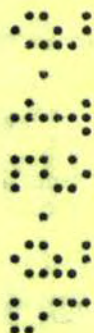
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Material Safety Data Sheet



BIO-SHIELD
BioShield Technologies Inc.

Bio-Shield Technologies, Inc.
4405 International Boulevard Ste B109
Norcross, Georgia 30093
Phone: (770) 925-3432

Bio-Shield

Protectant

Date Prepared: July 17, 1997 by J. Berkner
Replaces: June 5, 1996

EMERGENCY TELEPHONE
800-424-9300 (CHEMTREC)

Section 1: ----- Chemical Identification -----

PRODUCT NAME: BioShield Protectant
OTHER NAMES: DuraLast Protectant
Protectant

Section 2: ----- Hazardous Ingredients/Identity Information -----

NFPA Profile: Health 0 Flammability 1 Reactivity 0

Note: NFPA = National Fire Protection Association

HMIS Profile: Health 1 Flammability 1 Reactivity 0

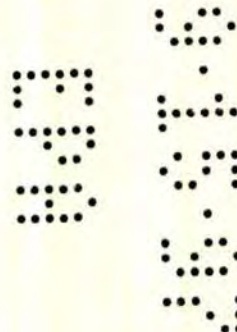
Note: HMIS = Hazardous Material Information System Ratings

CAS Number	Weight %	Component	Exposure Limit
27668-52-6	0.1-5	Octadecylaminodimethyltrimethoxysilyl ammonium chloride	N/A
57-55-6	0.1-5	Propane-diol	N/A
112-34-5	0-6	Diethylene glycol monobutyl ether	N/A
64-17-5	0-10	Ethyl alcohol	PEL, TWA 1000ppm
7732-16-5	balance	Water	

Note: The above information is not intended for use in preparing product specifications.

Section 3: ----- Physical/chemical characteristics -----

SOLUBILITY IN WATER: complete,
BOILING POINT: N/A
VAPOR PRESSURE: N/A
APPEARANCE AND ODOR: liquid, may contain dye and fragrance



Section 4: ----- Fire and Explosion Hazard -----

FLASH POINT : N/A*

Water based solution, non-flammable, might produce combustible vapors.

EXTINGUISHING MEDIA: N/A

SPECIAL FIREFIGHTING PROCEDURES: Self-contained breathing apparatus and protective clothing should be worn when fighting chemical fires.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None

HAZARDOUS PRODUCTS OF COMBUSTION: Forms carbon dioxide, carbon monoxide, silicon dioxide, hydrogen chloride, nitrogen oxides and products of incomplete combustion.

HAZARDOUS POLYMERIZATION: Will not occur

Section 6: ----- Health Hazard Data -----

FIRST AID PROCEDURES:

ROUTES OF ENTRY: Inhalation, Skin, Eye, Ingestion

EYES IMMEDEATELY flush eyes gently with a directed stream of water for at least 15 minutes, get medical attention.

SKIN Avoid skin contact. If symptoms occur and persist, seek medical attention.

INHALATION: Remove to fresh air. If symptoms persist get medical attention.

INGESTION If swallowed, seek medical attention.

Section 7: ----- Precautions for Safe Handling and Use -----

SMALL SPILL: Many spills may be cleaned up with rags by wiping and or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

LARGE SPILL: Stop spill at source, dike area of spill to prevent spreading, pump liquid to salvage tank. Ventilate area and wash spill site after material pickup is complete.

WASTE DISPOSAL METHOD: Dispose of product in accordance with applicable local, state and federal regulations.

STORAGE & HANDLING: Avoid freezing of liquid and skin contact with liquid.

Section 8: ----- Control Measures -----

RESPIRATORY PROTECTION: None

VENTILATION: To meet exposure limits (local and general)

PROTECTION: Wear eye protection, gloves,

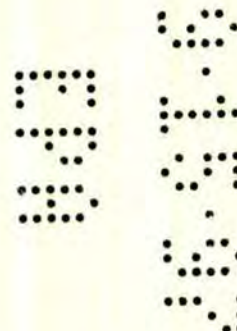
SKIN PROTECTION: Avoid skin contact, wash skin after contact with liquid. To prevent repeated or prolonged skin contact, wear impervious clothing, gloves and boots.

* N/A= Not Available

The information accumulated herein is believed to be accurate but is not warranted, whether originating with the company or not. Recipients are advised to confirm in advance of need that the information is current, applicable and suitable to their circumstances.

No warranty expressed or implied regarding the product described herein shall be created by or inferred from any statement or omission in the MSDS. This MSDS supersedes any previous MSDS for this product.

*** This is the last page ***

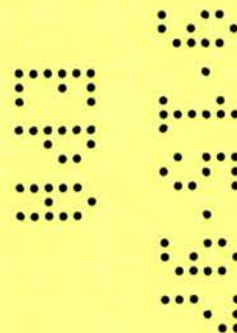


VOLUME V

Series 81

**Waiver Request of Requirement for Further Testing
for**

BST Protectant 50



WAIVER REQUEST OF REQUIREMENT FOR FURTHER TESTING

Test Type and Guideline Reference Number:

Acute Oral Toxicity	Guideline #81-1
Acute Dermal Toxicity	Guideline #81-2
Acute Inhalation Toxicity	Guideline #81-3
Primary Eye Irritation	Guideline #81-4
Primary Dermal Irritation	Guideline #81-5
Dermal Sensitization	Guideline #81-6

Test Substance: BST Protectant 50

BioShield Technologies, Inc.'s (BioShield) BST Protectant 50 is a domestic product containing an antimicrobial agent that eliminates and protects against germs and bacteria. The BST Protectant 50 contains the active ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride, a silicone quaternary ammonium salt, and is produced from the manufacturing use product BioShield AM 500 I [REDACTED]

[REDACTED] An application for registration of BioShield AM 500 I is pending at the Agency (EPA File Symbol 70871-E). In BST Protectant 50, BioShield AM 500 I is diluted to approximately 0.5% by weight active ingredient. All of the above-referenced studies have been conducted on DOW CORNING 5772. This waiver request pertains to the studies to be conducted using the end-use formulation, BST Protectant 50.

Summary

A waiver of requirement for the above-referenced six acute toxicity studies on BST Protectant 50 is requested based on existing toxicology data on DOW CORNING 5772, [REDACTED] DOW CORNING 5772 is 72% quaternary ammonium salt. BioShield's AM 500 I [REDACTED] contains 5% by weight active ingredient. BioShield's BST Protectant 50 is a further dilution of BioShield AM 500 I containing approximately 0.5% by weight active ingredient. The remaining ingredients in this product are water (approximately [REDACTED]) and the inert ingredients associated with the source of active ingredient. All of these inert ingredients are EPA-approved. Because BioShield's BST Protectant 50 contains approximately 0.5% active ingredient, the toxicity of BioShield AM 500 I would be significantly less than the toxicity of DOW CORNING 5772 which contains 72% active ingredient. Because of the significantly low concentration of active ingredient in BST Protectant 50, potential exposure to the active ingredient is

Product ingredient source information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

substantially reduced. Therefore, potential health hazards of BST Protectant 50 are not of any concern.

Basis for Waiver Request:

Existing Data

Acute toxicity studies on DOW CORNING 5772 exist in various animal species. The studies described below represent some of the critical studies conducted with this active ingredient. These studies have been accepted by EPA during reregistration of the active ingredient in DOW CORNING 5772. BioShield has been granted permission by Aegis (the present owner of the registration for DOW CORNING 5772) to cite these data in an acute toxicity waiver request in lieu of repeating the studies. No additional new information on acute toxicity of DOW CORNING 5772 would be generated by conducting these studies again with a significantly diluted formulation. These data may represent a worst-case scenario of exposure to BioShield's BST Protectant 50. The following is a list of studies that BioShield is citing:

MRID 40385201 Hobbs, E. (1973) Acute Toxicologic Properties of Dow Corning Q9-5700: Laboratory Project ID: AD-0003. Unpublished compilation prepared by DOW CORNING CORP.

MRID 42456511, Devries, C.; Siddiqui, W. (1983) Acute Oral Toxicity of DOW CORNING 5772 Antimicrobial Agent: Project X9-6346. Prepared by DOW CORNING CORP.

MRID 43219901, Devries, C.; Siddiqui, W. (1983) Acute Dermal Toxicity of DOW CORNING X9-6346 (DOW CORNING 5772 Antimicrobial Agent): Lab Project Number 4211-3. Unpublished study prepared by DOW CORNING CORP.

MRID 41157803, Kolesar, G., Siddiqui, W., Staton, E. (1985) An Acute Aerosol Inhalation Toxicity Study with DOW CORNING 5772 compound in Rats: Report No. 1312. Unpublished study prepared by DOW CORNING CORP.

MRID 93218047, Dwane, M. (1990) DOW CORNING CORP: An acute Dermal Irritation Study of DOW CORNING 5772 Antimicrobial Agent: Project X9-6346. Prepared by DOW CORNING CORP.

MRID 42456513 Devries, C.; Siddiqui, W. (1983) Phase 3 New Submission: Acute Dermal Irritation Study of DOW CORNING 5700 Antimicrobial Agent: Lab Project Number: X9-6346. Unpublished study prepared by DOW CORNING CORP.

MRID 42197401 Hoffman, R. (1992) A Skin Sensitization Study of DOW CORNING 5700 Hydrolysate in Guinea Pigs: Lab Project Number: 1992-I0000-36929. Unpublished study prepared by DOW CORNING CORP.

Exposure Potential From Intended Uses

BioShield's BST Protectant 50 contains only 0.5% active ingredient from BioShield AM 500 I. BioShield AM 500 I is a [REDACTED] containing approximately 5% of the active ingredient. Thus, the concentration of active ingredient in BST Protectant 50 is significantly reduced; [REDACTED] and 10 times less than that in BioShield AM 500 I. The exposure to BST Protectant 50 will be limited to the individuals present in the area treated and, because of its quick drying after surfaces have been treated with the product, further exposure would be minimal. In addition, the active ingredient in this product remains (dries) on the treated surface and does not get airborne; thus, inhalation exposure would be negligible. The product label outlines the appropriate use directions and precautions to be taken during its use. BioShield believes that because BST Protectant 50 is a [REDACTED] and it dries quickly after treatment of surfaces, the exposure hazards are very low.

Conclusion

Acute toxicity data of DOW CORNING 5772 on all above-mentioned studies (acute oral toxicity, Guideline #81-1; acute dermal toxicity, Guideline #81-2; acute inhalation toxicity, Guideline #81-3; primary eye irritation, Guideline #81-4; primary dermal irritation, Guideline #81-5; and dermal sensitization, Guideline #81-6) are available at the Agency. In addition, BioShield and Aegis have reached an agreement to share these data. BioShield believes that these studies support this request for a waiver from the requirement of acute toxicology data requirements for BST Protectant 50. BioShield believes that conducting additional studies will not provide new information on the toxicity of its product. Therefore, available data on DOW CORNING 5772 at the Agency justify the waiver of additional acute toxicity studies.

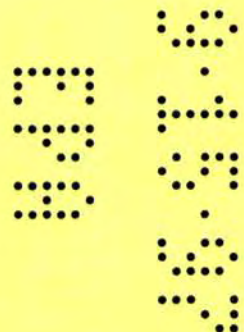
Product ingredient source information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

VOLUME V

Series 81

**Waiver Request of Requirement for Further Testing
for**

BST Protectant 50



AS
JC

WAIVER REQUEST OF REQUIREMENT FOR FURTHER TESTING

Test Type and Guideline Reference Number:

Acute Oral Toxicity	Guideline #81-1
Acute Dermal Toxicity	Guideline #81-2
Acute Inhalation Toxicity	Guideline #81-3
Primary Eye Irritation	Guideline #81-4
Primary Dermal Irritation	Guideline #81-5
Dermal Sensitization	Guideline #81-6

Test Substance: BST Protectant 50

BioShield Technologies, Inc.'s (BioShield) BST Protectant 50 is a domestic product containing an antimicrobial agent that eliminates and protects against germs and bacteria. The BST Protectant 50 contains the active ingredient 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride, a silicone quaternary ammonium salt, and is produced from the manufacturing use product BioShield AM 500 I [REDACTED]

[REDACTED] An application for registration of BioShield AM 500 I is pending at the Agency (EPA File Symbol 70871-E). In BST Protectant 50, BioShield AM 500 I is diluted to approximately 0.5% by weight active ingredient. All of the above-referenced studies have been conducted on DOW CORNING 5772. This waiver request pertains to the studies to be conducted using the end-use formulation, BST Protectant 50.

Summary

A waiver of requirement for the above-referenced six acute toxicity studies on BST Protectant 50 is requested based on existing toxicology data on DOW CORNING 5772. [REDACTED] DOW CORNING 5772 is 72% quaternary ammonium salt. BioShield's AM 500 I [REDACTED] contains 5% by weight active ingredient. BioShield's BST Protectant 50 is a further dilution of BioShield AM 500 I containing approximately 0.5% by weight active ingredient. The remaining ingredients in this product are water (approximately [REDACTED]) and the inert ingredients associated with the source of active ingredient. All of these inert ingredients are EPA-approved. Because BioShield's BST Protectant 50 contains approximately 0.5% active ingredient, the toxicity of Bioshield AM 500 I would be significantly less than the toxicity of DOW CORNING 5772 which contains 72% active ingredient. Because of the significantly low concentration of active ingredient in BST Protectant 50, potential exposure to the active ingredient is [REDACTED]

Product ingredient source information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

substantially reduced. Therefore, potential health hazards of BST Protectant 50 are not of any concern.

Basis for Waiver Request:

Existing Data

Acute toxicity studies on DOW CORNING 5772 exist in various animal species. The studies described below represent some of the critical studies conducted with this active ingredient. These studies have been accepted by EPA during reregistration of the active ingredient in DOW CORNING 5772. BioShield has been granted permission by Aegis (the present owner of the registration for DOW CORNING 5772) to cite these data in an acute toxicity waiver request in lieu of repeating the studies. No additional new information on acute toxicity of DOW CORNING 5772 would be generated by conducting these studies again with a significantly diluted formulation. These data may represent a worst-case scenario of exposure to BioShield's BST Protectant 50. The following is a list of studies that BioShield is citing:

MRID 40385201 Hobbs, E. (1973) Acute Toxicologic Properties of Dow Corning Q9-5700: Laboratory Project ID: AD-0003. Unpublished compilation prepared by DOW CORNING CORP.

MRID 42456511, Devries, C.; Siddiqui, W. (1983) Acute Oral Toxicity of DOW CORNING 5772 Antimicrobial Agent: Project X9-6346. Prepared by DOW CORNING CORP.

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Exposure Potential From Intended Uses

BioShield's BST Protectant 50 contains only 0.5% active ingredient from BioShield AM 500 I. BioShield AM 500 I is [REDACTED] containing approximately 5% of the active ingredient. Thus, the concentration of active ingredient in BST Protectant 50 is significantly reduced; [REDACTED] and 10 times less than that in BioShield AM 500 I. The exposure to BST Protectant 50 will be limited to the individuals present in the area treated and, because of its quick drying after surfaces have been treated with the product, further exposure would be minimal. In addition, the active ingredient in this product remains (dries) on the treated surface and does not get airborne; thus, inhalation exposure would be negligible. The product label outlines the appropriate use directions and precautions to be taken during its use. BioShield believes that because BST Protectant 50 is a [REDACTED] and it dries quickly after treatment of surfaces, the exposure hazards are very low.

Conclusion

Acute toxicity data of DOW CORNING 5772 on all above-mentioned studies (acute oral toxicity, Guideline #81-1; acute dermal toxicity, Guideline #81-2; acute inhalation toxicity, Guideline #81-3; primary eye irritation, Guideline #81-4; primary dermal irritation, Guideline #81-5; and dermal sensitization, Guideline #81-6) are available at the Agency. In addition, BioShield and Aegis have reached an agreement to share these data. BioShield believes that these studies support this request for a waiver from the requirement of acute toxicology data requirements for BST Protectant 50. BioShield believes that conducting additional studies will not provide new information on the toxicity of its product. Therefore, available data on DOW CORNING 5772 at the Agency justify the waiver of additional acute toxicity studies.

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Manufacturing process information may be entitled to confidential treatment

VOLUME V

Series 81

**Waiver Request of Requirement for Further Testing
for**

BST Protectant 50

50

WAIVER REQUEST OF REQUIREMENT FOR FURTHER TESTING

Test Type and Guideline Reference Number:

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Acute Dermal Toxicity	Guideline #81-2
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Test Substance: BST Protectant 50

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[REDACTED] An application for registration of BioShield AM 500 I is pending at the Agency (EPA File Symbol 70871-E). In BST Protectant 50, BioShield AM 500 I is diluted to approximately 0.5% by weight active ingredient. All of the above-referenced studies have been conducted on DOW CORNING 5772. This waiver request pertains to the studies to be conducted using the end-use formulation, BST Protectant 50.

Summary

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substantially reduced. Therefore, potential health hazards of BST Protectant 50 are not of any concern.

Basis for Waiver Request:

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Exposure Potential From Intended Uses

BioShield's BST Protectant 50 contains only 0.5% active ingredient from BioShield AM 500 I. BioShield AM 500 I is [REDACTED] containing approximately 5% of the active ingredient. Thus, the concentration of active ingredient in BST Protectant 50 is significantly reduced; [REDACTED] and 10 times less than that in BioShield AM 500 I. The exposure to BST Protectant 50 will be limited to the individuals present in the area treated and, because of its quick drying after surfaces have been treated with the product, further exposure would be minimal. In addition, the active ingredient in this product remains (dries) on the treated surface and does not get airborne; thus, inhalation exposure would be negligible. The product label outlines the appropriate use directions and precautions to be taken during its use. BioShield believes that because BST Protectant 50 is a [REDACTED] and it dries quickly after treatment of surfaces, the exposure hazards are very low.

Conclusion

Acute toxicity data of DOW CORNING 5772 on all above-mentioned studies (acute oral toxicity, Guideline #81-1; acute dermal toxicity, Guideline #81-2; acute inhalation toxicity, Guideline #81-3; primary eye irritation, Guideline #81-4; primary dermal irritation, Guideline #81-5; and dermal sensitization, Guideline #81-6) are available at the Agency. In addition, BioShield and Aegis have reached an agreement to share these data. BioShield believes that these studies support this request for a waiver from the requirement of acute toxicology data requirements for BST Protectant 50. BioShield believes that conducting additional studies will not provide new information on the toxicity of its product. Therefore, available data on DOW CORNING 5772 at the Agency justify the waiver of additional acute toxicity studies.

Product ingredient source information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

REPORT TITLE

Physical and Chemical Properties of
BST Protectant 50

DATA REQUIREMENTS

#63-2	Color
#63-3	Physical State
#63-4	Odor
#63-7	Density
#63-12	pH
#63-18	Viscosity

SPONSOR

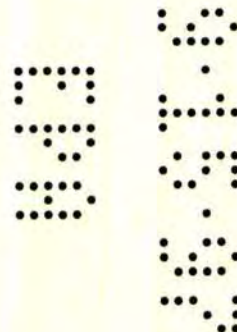
BioShield Technologies, Inc.
4405 International Boulevard, Suite B109
Norcross, GA 30093

SPONSOR'S REPRESENTATIVE

Jellinek, Schwartz & Connolly, Inc.
1525 Wilson Boulevard, Suite 600
Arlington, Virginia 22209

REPORT DATE

September 12, 1997



REPORT TITLE

Certification of Limits and
Analytical Method for Enforcement of Limits for
BST Protectant 50

DATA REQUIREMENTS

Pesticide Assessment Guidelines

#62-2, Certification of Limits
#62-3, Analytical Method for Enforcement of Limits

SPONSOR

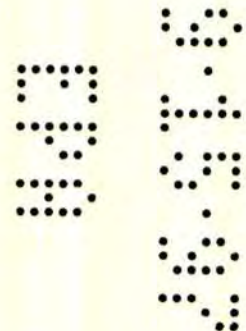
BioShield Technologies, Inc.
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SPONSOR'S REPRESENTATIVE

Jellinek, Schwartz & Connolly, Inc.
1525 Wilson Boulevard, Suite 600
Arlington, Virginia 22209

REPORT DATE

September 12, 1997



REPORT TITLE

Product Identity of
BST Protectant 50

DATA REQUIREMENTS

Pesticide Assessment Guideline

#61-1, Product Identity and Disclosure of Ingredients
#61-2, Description of Beginning Materials and Manufacturing Process
#61-3, Discussion of Formation of Impurities

SPONSOR

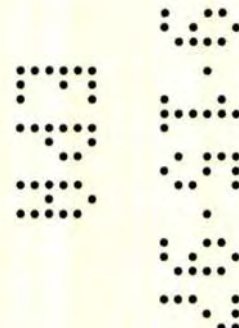
BioShield Technologies, Inc.
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Jellinek, Schwartz & Connolly, Inc.
1525 Wilson Boulevard, Suite 600
Arlington, Virginia 22209

REPORT DATE

September 12, 1997



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

SEP 22 1997

BIOSHIELD TECHNOLOGIES, INC.
4405 INTERNATIONAL BLVD.
SUITE B109
NORCROSS, GA 30093

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/15/97. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 16, 1997

• BIOSHIELD TECHNOLOGIES, INC
C/O JELLINEK, SCHWARTZ & CONNOLLY, INC
1525 WILSON BLVD, STE 600
ARLINGTON, VA 22209

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ATTN: BLANE DAHL

PRODUCT NAME: BST PROTECTANT 50
COMPANY NAME: BIOSHIELD TECHNOLOGIES, INC
OPP IDENTIFICATION NUMBER: 233279
EPA FILE SYMBOL: 70871-U
EPA RECEIPT DATE: 09/15/97

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT

The Office of Pesticide Programs has received your application for a new registration, and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Velma Noble, Product Manager 31 at (703) 308-6233.

Sincerely,

Front End Processing Staff
Information Services Branch
Program Management and Support Division



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BioShield Technologies, Inc.

4405 International Boulevard, Suite B109
Norcross, GA 30093

BST Protectant 50

ANTI-MICROBIAL AGENT & PROTECTANT

Mold, Mildew, & Odor Protectant Concentrate
Imparts Antimicrobial/Antibacterial Properties
Long-Lasting Antimicrobial/Antimicrobial Protection
Long-Lasting Protection from Mold and Mildew
Provides a Durable and Invisible Antimicrobial/Antibacterial Coating
Long-Lasting Protection from Bacteria and Germs
Long-Lasting Odor Protection
Molecularly Bonds to Provide Lasting Protection
Molecularly Bonds to Remain Active on Surface
Not Destroyed by Repeated Cleaning
Eliminates Odor at the Source
Prevents Deterioration Caused by Bacteria
Eliminates Odors
Antibacterial Action
Kills Viruses, Bacteria, Mold & Mildew
Long-Lasting Protection
Provides Long-Lasting Protection by Forming an Invisible Barrier
Removes Contaminates
Eliminates Odors at the Source
Lightly Scented

Kills Bacteria, Mold & Mildew
Removes Viruses, Kills Bacteria, Mold & Mildew
Removes Contaminates (That Cause Allergies)
Protects and Disinfects
Use on Carpet and Upholstery to Keep Carpet and Upholstery Bacteria Free (Free From Odor Causing Bacteria) (Germ Free), up to 3 Months
Keeps Killing Bacteria and Mildew up to 3 Months (After Application)
Invisibly Bonds to Most Materials for Lasting Protection up to 3 Months
Long-Lasting Protection Against Mold, Mildew, Bacteria, and Odor (for up to 3 Months)
Long-Lasting Antimicrobial (Antibacterial) Protection, (up to 3 Months)
Molecularly Bonds for Continuous Protection for up to 3 Months
Remains Effective up to 3 Months by Invisibly Bonding Disinfectant
Disinfectant with Residual Activity
Disinfects Carpet and Upholstery
Disinfects Bathrooms (Up to 3 Months)
Antimicrobial/Antibacterial Disinfectant
Disinfects Up to 3 Months

Active Ingredient:

3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride

Inert Ingredients :

0.50%
99.50%
100.00%

*includes polymer derivatives and wetting agents

KEEP OUT OF REACH OF CHILDREN

Caution

EPA Reg. No. xxxx-xx

EPA EST. xxxxx-GA-xx

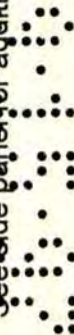
Lot No.



STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

See side panel for additional precautionary statements



PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Caution: May be harmful if swallowed or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

BST Protectant 50 should be diluted with one to four parts water. For most effective treatment, dilute BST Protectant 50 with one part water. BST Protectant 50 is still effective when diluted with four parts water, especially when applied regularly.

For effective and lasting protection, up to 3 months, wet PRE-CLEANED surface with diluted BST Protectant 50 thoroughly. Let stand several minutes and wipe dry with cloth or sponge. For most effective treatment, let stand until dry, wipe with moist cloth or sponge if spotting occurs. For application on fabrics, test for staining and color-fastness by applying protectant to a small, concealed area prior to use.

APPROVED USES

BST Protectant 50 is approved as a sanitizer and microbiocide for use in laundry, carpet treatment, upholstery and drapery treatment, and building cleaning and treatment.

BST Protectant 50 can be used to impart durable, long-lasting, antimicrobial protection to substrates for the following applications:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass duct board;
- Fire hose fabric;

- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

• BJT Protectant 50 can be used to impart durable, long-lasting broad-spectrum, antimicrobial protection to substrates. Examples of areas and materials for use of Protectant:

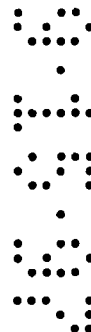
- Patio Furniture
- Shower Curtains
- Shower Stalls
- Toilet areas
- Canvas
- Vinyl
- Fiberglass
- Wood
- Plastic
- Upholstery
- Fabrics
- Indoor/Outdoor carpet
- Throw Rugs
- Bath Mats

- Floor Mats
- Concrete
- Countertops (not including food-contact surfaces)
- Car/Truck interiors
- Cabinets (not including food-contact surfaces)
- Sinks
- Draperies
- Window treatments
- Wallets
- Garbage Containers
- Clothing
- Jackets
- Shoes

STORAGE AND DISPOSAL

Storage: Store in original container at temperatures above freezing in areas inaccessible to children.

Disposal: Do not reuse empty bottle. Wrap bottle and put in trash



COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109
Norcross, GA 30093

Information About Antimicrobial Agents

BST Protectant 50

U.S. Environmental Protection

Agency Registration Number.....

Type Silicone quaternary ammonium salt

Physical Form Low-viscosity liquid

Special Properties..... Surface bondability

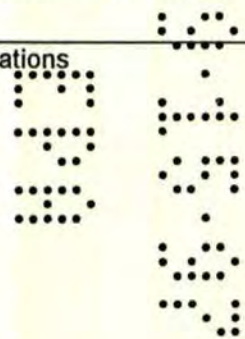
Primary Uses A sanitizers and microbiocides for laundry treatment,
carpet treatment, upholstery and drapery treatment,
and building cleaning and treatment to give a
surface-durable antimicrobial treatment effective and active
against a wide variety of bacteria, fungi, algae and yeasts

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications*

Structure.....	$ \begin{array}{c} \text{CH}_3 \\ \\ [(\text{CH}_3\text{O})_3\text{Si}(\text{CH}_2)_3\text{N}-\text{C}_{18}\text{H}_{37}]^+\text{Cl}^- \\ \\ \text{CH}_3 \end{array} $
Concentration.....	0.50%
Appearance.....	Colorless liquid
Solubility.....	Miscible in all proportions with water, ethanol, and methanol
Thermal Stability °C (°F).....	Stable when stored at or below 30°C (86°F)

* Specification Writers: Please contact BioShield for information regarding specifications



DESCRIPTION

BST Protectant 50 is BioShield's designation for a water based solution containing the active ingredient 3-(trimethoxysilyl) propyloctadecyldimethyl ammonium chloride. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

BST Protectant 50 offers users the following features:

- Good durability— BST Protectant 50 imparts durable, broad-spectrum, biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact.
- Long-lasting activity—active by leaving an invisible, protective bonded shield on surface.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of BST Protectant 50.

BENEFITS

The following benefits are derived when BST Protectant 50 is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Non-leaching, the antimicrobial remains invisibly bonded and active on most surfaces.
- Continuous disinfection of most surfaces by residual activity.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde.
- Product performance with little degradation up to 375°F.

Materials treated with BST Protectant 50 are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. BST Protectant 50 inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. BST Protectant 50 forms a coating on a wide variety of substrates and antimicrobial action is exhibited on contact.

APPROVED USES

BST Protectant 50 is approved as a sanitizer and microbiocide for use in laundry, carpet treatment, upholstery and drapery treatment, and building cleaning and treatment.

BST Protectant 50 can be used to impart durable, long-lasting, antimicrobial protection to substrates for the following applications:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

BST Protectant 50 can be used to impart durable, long-lasting broad-spectrum, antimicrobial protection to substrates. Examples of areas and materials for use of Protectant:

- Patio Furniture
- Shower Curtains
- Shower Stalls
- Toilet areas
- Canvas
- Vinyl
- Fiberglass
- Wood
- Plastic
- Upholstery
- Fabrics
- Indoor/Outdoor carpet
- Throw Rugs
- Bath Mats
- Floor Mats
- Concrete
- Countertops (not including food contact surfaces)
- Car/Truck interiors
- Cabinets (not including food contact surfaces)
- Sinks
- Draperies
- Window treatments
- Wallets
- Garbage Containers
- Clothing
- Jackets
- Shoes

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

For effective and lasting protection, up to 3 months, wet PRE-CLEANED surface thoroughly. Let stand several minutes and wipe dry with cloth or sponge. For most effective treatment, let stand until dry, wipe with moist cloth or sponge if spotting occurs. For application on fabrics, test for staining and color-fastness by applying protectant to a small, concealed area prior to use.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Caution: May be harmful if swallowed or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

STORAGE AND DISPOSAL

Storage: Store in original container at temperatures above freezing in areas inaccessible to children.

Disposal: Do not reuse empty bottle. Wrap bottle and put in trash

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

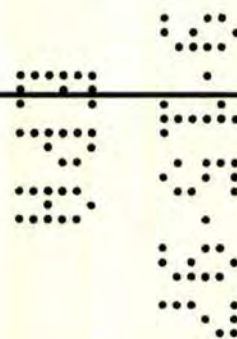
PATENT INFRINGEMENT

Recommendations or suggestions for use should not be interpreted as inducements to infringe any patents.

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4. Venter, J.E., J.E. Dixon, P.R. Maroko and N.O. Kaplan. "Biologically Active Catecholamine Covalently Bound to Glass Bead." *Proc. Nat. Acad. Sci. (U.S.A.)*. 1972, 69:1141-1145.
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6. Isquith, A.J., E.A. Abbott and P.A. Walters. "Surface-Bonded Antimicrobial Activity of an Organosilicon Ammonium Chloride." *Appl. Microbial.*, 1972, 24:859-863.
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9. Malek, J.R. and J.L. Speier. "Development of an Organosilicone Antimicrobial Agent for the Treatment of Surfaces." *J. Coated Fabrics*, 1992, 12:38-45.
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14. Hales, M.G., M.E. Sorkin and W.C. White. "Antimicrobial Treatments, Part II: Types and Considerations for Use." *Cleaning and Restoration*, 1986, Vol. 24, Num. 4, 13-15.
15. Hales, M.G. and W.C. White. "Antimicrobial Treatments, Part III: Methods for Determining Their Effectiveness." *Cleaning and Restoration*, 1986. May, 18-20.
16. Battice, D.R. and M.G. Hales. "A New Technology for Producing Stabilized Foams Having Antimicrobial Activity." *Journal of Cellular Plastics*, 1985, Vol. 21, Num. 5, 332-337.

BioShield Technologies, Inc.
4405 International Boulevard, Suite B109
Norcross, GA 30093



BioShield AM 500 I

ANTI-MICROBIAL AGENT & PROTECTANT

A Silicone Quaternary Ammonium Salt
(For Manufacturing Use Only)

Active Ingredient:	3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride.....	5.0%
Inert Ingredients:	95.0%
		<u>100.0%</u>

**KEEP OUT OF REACH OF CHILDREN
DANGER**

Lot No. _____ EPA Reg. No. xxxx-xx EPA EST. xxxx-GA-xx

NET CONTENTS: 8 oz., 1 gal., 5 gal., or 55 gal.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.
IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

De-activation of AM 500 I can be achieved by the addition of anionic surfactant in quantity equivalent to that of AM 500 I.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

SEE COLLATERAL LABEL FOR COMPLETE USE DIRECTIONS

NOTE: This product should not be used or compounded with any bleach or oxidizing agents. Do not use in conjunction with anionic surfactants.

For formulating use into end-use products listed in the attached "Information About Antimicrobial Agents" pamphlet.

APPROVED USES

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and carpet treatment products, and building cleaning and treatment products.

AM 500 can be used to impart durable, broad-spectrum, antimicrobial protection to substrates for the following applications:

- Air filters for furnaces air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;

- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, tightly closed containers below 30°C (86°F) and above 0°C (32°F) in a secure area inaccessible to children and away from food or feed. AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MORE INFORMATION CONCERNING THIS PRODUCT, PLEASE CONSULT THE MATERIAL SAFETY DATA SHEET (MSDS). THE MSDS CAN BE OBTAINED BY WRITING BIOSHIELD TECHNOLOGIES, INC. AT 4405 INTERNATIONAL BOULEVARD, SUITE B109, NORCROSS, GEORGIA, 30093.

COLLATERAL LABELING

BioShield Technologies, Inc.

4405 International Boulevard, Suite B109
Norcross, GA 30093

Information About Antimicrobial Agents

AM 500 I — FOR MANUFACTURING USE ONLY

U.S. Environmental Protection

Agency Registration Number.....

TypeSilicone quaternary ammonium salt

Physical FormLow-viscosity liquid

Special Properties.....Surface bondability

Primary UsesAs an active ingredient for formulating disinfectants,
sanitizers and microbiocides for use in laundry additives,
carpet treatment products, upholstery and drapery
treatment products, and building cleaning and
treatment products to give a surface-durable
antimicrobial treatment effective and active against
a wide variety of bacteria, fungi, algae and yeasts

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications*

Structure.....	$ \begin{array}{c} \text{CH}_3 \\ \\ [(\text{CH}_3\text{O})_3\text{Si}(\text{CH}_2)_3\text{N}-\text{C}_{18}\text{H}_{37}]^+\text{Cl}^- \\ \\ \text{CH}_3 \end{array} $
Concentration.....	5.0%
Appearance.....	Colorless liquid
Solubility.....	Miscible in all proportions with water, ethanol, and methanol
Thermal Stability °C (°F).....	Stable to 30°C (86°F)

*Specification Writers: Please contact BioShield for information regarding specifications

DESCRIPTION

AM 500 I is BioShield's designation for 3-(trimethoxysilyl) propyloctadecyldimethyl ammonium chloride containing 5 percent active ingredient by weight. Alkoxysilanes of this nature have been shown to form durable bonded coatings to a number of materials (see "References" section).

AM 500 I offers users the following features:

- Good durability—BIOSHIELD AM 500 I Antimicrobial Agent imparts durable, broad-spectrum, biostatic activity to the surface of a wide variety of substrates; it is leach-resistant and nonmigrating and is not consumed by microorganisms.
- Broad-spectrum activity—effective against gram positive and gram negative bacteria, fungi, algae and yeasts; antimicrobial action is exhibited on contact.
- Increased efficiency—through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with a minimum amount of AM 500 I.

BENEFITS

The following benefits are derived when a formulation containing the active ingredient is applied to a surface:

- Provides hygienic freshness and combats deterioration caused by bacteria, fungi, algae, and yeasts.
- Inhibits growth of bacteria and mildew on the treated article.
- Prolongs the life of a article by inhibiting the growth of bacteria and mildew.
- Provides a durable, residual, antimicrobial treatment that is not destroyed by repeated cleaning.
- Resists development of bacterial and fungal odors.
- Retains freshness by resisting the growth of odor-causing bacteria and mildew (fungus).
- Provides a chemical treatment that enables fabrics to resist odors.
- Provides a unique chemical treatment that resists mildew and bacteria growth and imparts odor resistance.
- Contains no phenols, tin, heavy metals, lead, mercury, or formaldehyde.
- Product performance with little degradation up to 375°F.

Materials treated with formulations containing the antimicrobial agent AM 500 I are preserved by the bacteriostatic, fungistatic and algistatic action imparted by the active ingredient. AM 500 I inhibits the growth of microorganisms that are responsible for causing odor, discoloration and deterioration. It also provides residual inhibition of microorganisms to aid in the control of these deleterious effects. AM 500 I forms a coating on a wide variety of substrates and antimicrobial action is exhibited on contact.

APPROVED USES

AM 500 I is approved for use in formulating disinfectants, sanitizers and microbiocides for use in laundry additives, carpet treatment products, upholstery and drapery treatment products, and building cleaning and treatment products.

AM 500 can be used to impart durable, broad-spectrum, antimicrobial protection to substrates for the following applications:

- Air filters for furnaces, air-conditioners, air purification devices, automobiles, recirculating air handling systems;
- Air filters/materials;
- Aquarium filter material;
- Bed sheets, blankets, and bedspreads;
- Buffer pads (abrasive and polishing);
- Carpets and draperies;
- Fiberfill for upholstery, sleeping bags, apparel, etc., where the fiber is cotton, natural down, nylon, polyester, rayon, or wool;
- Fiberglass ductboard;
- Fire hose fabric;
- Humidifier belts;
- Mattress pads and ticking;
- Men's underwear and outerwear;
- Non-woven disposable diapers;
- Non-woven polyester;
- Outerwear apparel;
- Disposable polyurethane foam cushions for Lapidus Airfloat Systems;
- Polyurethane foam for household, industrial, and institutional sponges and mops;
- Polyurethane and polyethylene foam, when covered;
- Polyurethane foam for packaging and cushioning in non-food contact applications;
- Polyurethane foam used as a growth medium for non-food crops and plants;
- Pre-moistened towelettes and tissue wipes (these do not impart pesticidal properties);
- Roofing materials - defined as shingles, roofing granules, wood shakes, felt, stone and synthetic overcoats;
- Sand bags, tents, tarpaulins, sails, and ropes;
- Athletic and casual shoes;
- Shoe insoles;
- Shower curtains;
- Socks comprised of nylon, nylon/orlon, cotton/nylon, linen/Lycra, acrylic/polypropylene/nylon/Lycra, wool/silk/nylon/Lycra and wool/acrylic/nylon/Lycra; provides residual self-sanitizing activity against athlete's foot fungus (*Trichophyton mentagrophytes*) on the sock, durable for up to 10 repeated washings; prevents 99.9 percent of the growth of athlete's foot fungus on the sock;
- Throw rugs;
- Toweling made of 100 percent cotton, 100 percent polyester, and blends of the two fibers;
- Toilet tank and seat covers;
- Umbrellas;
- Upholstery made of acetates, acrylics, cotton, fiberglass, nylon, polyester, polyethylene, polyolefins, polypropylene, rayon, spandex, vinyl, and wool;
- Vacuum cleaner bags and filters;
- Vinyl paper-wallpaper for non-food contact surfaces;
- Disposable wiping cloths that can be used for multiple purposes such as dusting or washing furniture, cars, walls, windows, floors, appliances, dishes, counter tops, etc.; the wiping cloths do not impart pesticide properties;
- Women's hosiery; and
- Women's intimate apparel.

DIRECTIONS FOR USE

AM 500 I can be incorporated directly into formulations used to make the end products listed in this bulletin.

AM 500 I can also be diluted with water or other solvents (for example, alcohol, and ketones) and then applied to organic or inorganic substrates by brushing, dipping, padding, soaking, spraying, fogging or by using foam finishing techniques to give a final treatment of 0.1 to 1.0 percent by weight active ingredient.

After applying the antimicrobial agent, the substrate can then be dried at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Optimum application and drying conditions, such as time and temperature, should be determined for each application before use.

EPA REGISTRATION REQUIREMENTS

The applications for which this product are used require approval by the Environmental Protection Agency on an end-use basis in regard to claims made thereof. Formulators are responsible for satisfying registration requirements for their products.

PRECAUTIONARY STATEMENTS

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Causes skin irritation. Harmful if absorbed through skin or inhaled. Harmful if inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wear protective clothing and gloves, and protective eyewear (goggles and face shield). Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark; this product might be toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

AM 500 I, by standard biological oxygen demand (BOD) and total oxygen demand (TOD) determination, does not appear to be biodegradable. Potential harm to the environment is minimized, however, because of the minimal amount of chemical applied and its durable coupling to surfaces.

Inactivation of solutions containing AM 500 I may be accomplished by one of the following methods:

- addition of an anionic surfactant or detergent in quantity equivalent to that of AM 500 I in solution; or
- addition of Triton X-100 nonionic detergent at a final concentration of 10,000 ppm (1.0 percent volume/volume) or greater to bath solutions up to 1.0 percent volume/volume of AM 500 I.

Every effort should be made to contain accidental spills of AM 500 I to the immediate area. This may be accomplished by the use of sandbags to confine the spill to facilitate cleanup and disposal. Contaminated sand may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags by wiping and/or mopping and allowing the liquid to absorb into the fabric. The rags may then be disposed of by incineration.

Floor drains in areas of material use should be protected with sandbags to contain accidental spills.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in original, unopened containers below 3°C (86°F) and above 0°C (32°F). AM 500 I has a minimum shelf life of 12 months from the date of shipment from BioShield.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Before handling, read product label in its entirety

IMPORTANT: WARRANTY AND DISCLAIMER INFORMATION

BioShield Technologies, Inc., warrants that the product conforms to its chemical description and is reasonably fit for the purposes stated in this bulletin when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to bulletin instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

BIOSHIELD SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

REFERENCES

1. Hough, J.S. and T.P. Lyons. "Coupling of Enzymes On a Microorganisms" *Nature*. London, 1972, 235-289.
2. Johannsen, O.K., F.O. Stark, G.E. Vogel and R.M. Fleishmann. "Evidence for Chemical Bond Formation at Silane Coupling Agent Interfaces." *J. Compos. Mater.*, 1967, 1:278-292.
3. Plueddemann, I.P. "Adhesion Through Silane Coupling Agents." *J. Adhesion*, 1970, 2:184-201.
4. Venter, J.E., J.E. Dixon, P.R. Maroko and N.O. Kaplan. "Biologically Active Catecholamine Covalently Bound to Glass Bead." *Proc. Nat. Acad. Sci. (U.S.A.)*. 1972, 69:1141-1145.
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6. Isquith, A.J., E.A. Abbott and P.A. Walters. "Surface-Bonded Antimicrobial Activity of an Organosilicon Ammonium Chloride." *Appl. Microbial.*, 1972, 24:859-863.
7. Gettings, R.L. and B.L. Triplett. "New Durable Antimicrobial Finish for Textiles." *ATCC Book of Papers—1978 Nat. Tech. Conf.*, 1978, 259-261.
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9. Malek, J.R. and J.L. Speier. "Development of an Organosilicone Antimicrobial Agent for the Treatment of Surfaces." *J. Coated Fabrics*, 1992, 12:38-45.


10. Speier, J.L. and J.R. Malek. "Destruction of Microorganisms by Contact With Solid Surfaces." *J. Colloid Interface Science*, 1982, 89-68-76.
11. Siddiqui, W.H., J.R. Malek, E. Stanton and E. J. Hobbs. "Percutaneous Absorption of an Antimicrobial Organosilicon Quaternary Ammonium Chloride in Rabbits." *J. Appl. Toxicol.*, 1983, 3.3:146-149.
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13. Hales M.G., M.E. Sorkin and W.C. White. "Antimicrobial Treatments, Part I: What They are and Why They Are Used." *Cleaning and Restoration*." 1986, March, 14-15.
14. Hales, M.G., M.E. Sorkin and W.C. White. "Antimicrobial Treatments, Part II: Types and Considerations for Use." *Cleaning and Restoration*", 1986, Vol. 24, Num. 4, 13-15.
15. Hales, M.G. and W.C. White. "Antimicrobial Treatments, Part III: Methods for Determining Their Effectiveness." *Cleaning and Restoration*", 1986. May, 18-20.
16. Battice, D.R. and M.G. Hales. "A New Technology for Producing Stabilized Foams Having Antimicrobial Activity." *Journal of Cellular Plastics*, 1985, Vol. 21, Num. 5, 332-337.

BioShield Technologies, Inc.
4405 International Boulevard, Suite B109
Norcross, GA 30093

NIFT

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060 Approval Expires 5-31-98

 EPA United States Environmental Protection Agency Washington, DC 20460	<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number 233279
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Application for Pesticide - Section I

1. Company/Product Number 70871-1)	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BST Protectant 50	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) BioShield Technologies, Inc. 4405 International Boulevard, Suite B109 Norcross, GA 30093 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

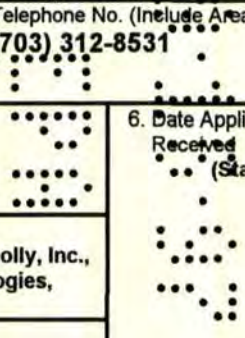

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)**Application for Pesticide Registration****Section - III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Package wgt. No. Per Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2 - 24 ounce containers	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)			
Name Blane Dahl	Title Registration Manager, Jellinek, Schwartz & Connolly, Inc., Authorized Representative of BioShield Technologies, Inc.	Telephone No. (Include Area Code) (703) 312-8531	
Certification I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 	
2. Signature 	3. Title Registration Manager, Jellinek, Schwartz & Connolly, Inc., Authorized Representative of BioShield Technologies, Inc.		
4. Typed Name Blane Dahl	5. Date September 12, 1997		



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

233279

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

-VOID-

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

233279

233279

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

- VOID -

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

